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1.0 Summary

Supply partnership management is a key enabler for the successful implementation of the Technology Roadmap. The high cost implications for up-front investment in new facilities is no longer sustainable for the expected rate of growth and the widening portfolio of biopharmaceutical products over the next 5–10 years that the roadmap covers. Likewise, the cost to supply materials and services are also significant in the new biomanufacturing scenarios based on single-use or disposable systems (e.g. cell culture media, resins and Protein A), being recognized as some of the highest contributors to the cost modeling used to support this Technology Roadmap.

The value chain for biopharmaceuticals contains an important speed element that supply partnership management can positively impact – the speed to produce clinical materials and to get the first product to market, and the scale up to full production, all rely heavily on the interaction between supply partners and the biomanufacturers involved. The speed of change for the value chain is also an important driver for innovation that has to be balanced with the impact on quality.

The cost of non-quality, caused by issues such as raw material variability and a lack of understanding and control of the supply chain, is perceived as high in the current state of the industry and needs to be driven out.

Flexibility in supply partnership management is important. With respect to the drivers identified by the Technology Roadmap Team, flexibility pertains to the aspects of adopting shared best practices and embracing the opportunities afforded to the biopharmaceutical industry by the 4th industrial revolution as it embarks on progressing down the Technology Roadmap.

A big step change is needed in the way that supply partners and biopharmaceutical companies interact with each other. There needs to be a significant development in the openness and trust that exists between supply partners and biomanufacturers. This will allow the harmonization of methods and levels of interaction and data exchange seen in other high technology, fast-moving sectors, e.g. the semiconductor industry, robotics, software development and high-performance engineering (automotive and aerospace), where the evolution of supply partnership has become much more symbiotic than purely transactional.

Imagine a world where production data was shared, analyzed and instantly available to both supply partners and biopharmaceutical manufacturers. Where duplication of test and release data was not necessary because there was sufficient trust in the data generated. Where feedback mechanisms existed to allow production and quality performance to be constantly improved. Where supply chains were not just the responsibility of the direct tier 1 supply partner but were the joint responsibility of all parties within the supply chain and focused on security and quality of supply for the patient.

The key challenge to this idealized state for supply partnership management is the development of the relationships between biopharmaceutical manufacturers and their supply partners. The winners will be those that find a way where sharing objectives and aims can be done in a safe, secure and collaborative way, which still allows for business targets to be achieved equitably and intellectual property (IP) to be protected and that works with the health authorities that regulate the industry. To break this down for this first edition of the Technology Roadmap, the key areas considered are:

- openness and trust
- standardization
- electronic data exchange (EDE) and supplier integration
- quality built-in
- forecasting and demand planning.
2.0 Introduction

2.1 Vision

The overall Technology Roadmap is naturally a combination of work by both the biopharmaceutical base and the supply base to develop a plan and define future targets as an industry. The goal is to influence the direction and decision making in the industry as firms develop new technologies for the future. The biopharmaceutical companies cannot do it on their own so they need to work in collaboration with the supply base to achieve their goals. So with each roadmap technical team inherently having biopharmaceutical companies and suppliers in ‘partnership’, why do we have a separate workstream for ‘supply partnership management’?

What makes this workstream different is that it focuses specifically on the relationship of the biopharmaceutical companies and the supply base – not specifically on one technology. The vision is to create a framework that will help supply partnerships be more effective and efficient for both sides.

In principle, this team sees a vision of the future characterized by a few fundamental elements:

- creating a ‘series’ of standards (materials, components, specifications, documentation, etc.), which allows for more efficient supply chain management and procurement processes between suppliers and manufacturers and enables increased volumes and business
- creating a new value proposition that focuses on delivery and performance in addition to the traditional focus on innovative technology. This allows customers to reward great manufacturers that sustain business and not just the great innovators that get selected early in the development cycle
- creating more flexibility/agility/interchangeability to lead to greater opportunities for suppliers for new/additional applications and to improve supply chain continuity
- creating lean and efficient supply chains driven by the ‘super’ integration of business systems between customers and suppliers.

2.2 Scope

The Supply Partnership Management Roadmap Team will focus on five key enablers that will help us deliver the industry vision. These are:

1. Openness and trust
   - a culture of openness and trust enabling the required information – both good and bad – to be shared across the supply chain in real time without fear of retribution
2. Standardization
   - a culture of driving standardization while continuing to support innovation
3. Electronic data exchange
   - integrating systems throughout the supply chain to create transparency across technology, process, demand planning and capacity between manufacturers and suppliers
4. Quality built-in
   - clear quality expectations established up front that result in suppliers consistently producing materials that meet regulatory and industry expectations, while building in quality at the source and driving to ‘zero defects’
5. Forecasting and demand planning
   - consolidated, transparent capacity planning for industry-critical raw materials and services
   - utilizing EDE and supplier integration of systems
   - risk analysis and business continuity planning.

The following topics are considered in or out of scope for this document.

In scope:

- supply chain sourcing and procurement
- how and where to establish standards/specifications within the supply chain
- supply quality and service performance
- how to incentivize the supply chain network (i.e. create a ‘new’ value proposition)
- tactical administrative/operational interactions (standard request for proposal, etc.)
- identifying which technology innovations should be standardized vs. left to traditional differentiation
- system, technical, commercial and quality process integration.

Out of scope:

- specific technical standards
- pricing
- strategic supplier management strategies
- sourcing strategies
- ongoing Bio-Process Systems Alliance, and Parenteral Drug Association standardization initiatives (i.e. stopper Acceptable Quality Limit specifications).
2.3 Benefits
The benefits of supply partnership management are realized when multiple companies work together towards a common objective. The combined effort provides a greater level of product knowledge and technical expertise. This will facilitate acceptance of new technologies into development and enable the companies to enter new markets with product revisions and breakthroughs. This requires supply chains and processes that:
- are safe, innovative, robust against supply disruption and sustainable
- are faster to develop, produce and make changes to products and processes – accelerating developing technology
- deliver lower cost and higher quality raw materials, services and lower capital expenditure investment – from R&D partnerships to finished product (including equipment, materials, software, services and consumables).

3.0 Scenario needs
Supply partnership management is an important and cross-cutting area of the Technology Roadmap to further the scenarios described in the Overview report:
Table 2. Supply partnerships are recognized as a means of developing future ways of working in the industry – bringing more value to its demand and supply sides, and accelerating the pace of innovation in alignment with the aims of the overall Technology Roadmap.

Table 1 presents components of the above enablers and highlights the importance of supplier expertise, efficiency and the optimization of results through innovation. This table is a navigator to guide the reader into the needs, challenges and potential solutions sections of this roadmap report. It is not comprehensive, but describes the structural interactions with suppliers (regardless of biomanufacturing scenario) and presents a developing ‘way of working’ in a supply partnership.

<table>
<thead>
<tr>
<th>Enabler</th>
<th>Collaboration:</th>
</tr>
</thead>
</table>
| Openness and trust | • suppliers are an extension of the biomanufacturer  
• engagement with R&D teams early in the process to enable standardization of technology platforms  
• set clear technical and functional expectations and develop collaborations  
• end-user functional requirements are well defined and shared with supplier partners  
• agreements aligned with the project lifecycle and incentivized for both parties  
• co-owned design and validation packages for novel solutions  
• IP parameters and ownership defined at the start of projects. |

<table>
<thead>
<tr>
<th>Enabler</th>
<th>Development:</th>
</tr>
</thead>
</table>
| Openness and trust | • transparency to customer and supplier technologies and capabilities  
• shared objectives – guided development with milestone incentives  
• mutually agreed functional specifications  
• functional-based design and harmonized with industry standards. |

<table>
<thead>
<tr>
<th>Enabler</th>
<th>Regulatory:</th>
</tr>
</thead>
</table>
| Openness and trust | • process characterization and supplier controls to allow multiple options for process  
• supplier trusted data – comparable in content quality to user’s internally developed data packages  
• provision for plug-and-play with accountability of supplier for quality (additive manufacturing environment). |

Table 1: Key technologies and capabilities relevant to all biomanufacturing scenarios

<table>
<thead>
<tr>
<th>Enabler</th>
<th>EDE and supplier integration</th>
</tr>
</thead>
</table>
| Openness and trust | • common EDE standard for suppliers and end-users  
• common practice for secure self-serve data exchange portal for supplier and end-user provided data (e.g., change notifications, certificates of assurance, etc.)  
• common practice that customer demand will drive supplier manufacturing schedule in real-time via EDE  
• move to standards for data exchange, e.g. American Society for Testing and Materials (ASTM) guidelines as defined in WK51651  
• define process performance data that qualify the impact of raw material on end-user’s critical quality attributes (CQAs) to provide feedback to supplier. |

EDE - electronic data exchange, ASTM - American Society for Testing and Materials, CQA - critical quality attribute
### Table 1: Key technologies and capabilities relevant to all biomanufacturing scenarios (continued)

| Enabler | Standardization | Quality:  
|---------|-----------------|
|         | • industry standard audits and auditors  
|         | • cross-industry material specification agreement, quality assurance, metrics, supplier scorecard  
|         | • harmonization of testing requirements  
|         | • standardized 'batch' definition in continuous scenarios  
|         | • standardized supplier validation, e.g. factory acceptance testing, extractables and leachables, failure mode effects analysis, etc.  
|         | • standardize on the testing specification for material release.  
|         | Device:  
|         | • standardized ports, connectors (single-use), holders and housings, etc.  
|         | • standardized sensors/instruments, e.g. to meet input/output or network standard.  
|         | Equipment:  
|         | • unified technical specifications/site specifications  
|         | • unified automation specifications  
|         | • unified top requirements.  
|         | Quality built-in | Supplier dependency:  
|         | • reduced/removal of duplicate routine release testing for incoming raw material  
|         | • alignment of quality systems across the industry.  
|         | Quality requirements:  
|         | • industry-accepted templates for specifications  
|         | • guidelines for new, small suppliers (e.g. active pharmaceutical ingredients)  
|         | • environmental management/monitoring  
|         | • allow for more combinations or chemistries  
|         | • shared audits  
|         | • standard protocols.  
|         | Optimization:  
|         | • reduce suppliers’ internal testing requirements and release effort  
|         | • limit incoming inspection to identification confirmation and reduce warehousing  
|         | • fast and scalable prototyping  
|         | • reduce the qualification time for modular and mobile.  
|         | Forecasting and demand planning | • transparency to capacity planning at the supplier (tiers 1 and 2)  
|         | | • transparency to long- and short-term demand for biopharmaceutical companies – cross-industry  
|         | | • utilize EDE for real-time planning  
|         | | • industry supply chain risk analysis and harmonized mitigation strategies  
|         | | • shared business continuity planning for key supply chain constraints and risks.  

EDE - electronic data exchange, ASTM - American Society for Testing and Materials, CQA - critical quality attribute
4.0 Future needs, challenges and potential solutions

As part of the process for assessing future needs, challenges and potential solutions, the Supply Partnership Management Roadmap Team conducted an assessment of the 5- and 10-year metrics (for flexibility, speed, quality and cost) as detailed in the Overview report; Table 1. The assessment considered what the impact on overall metrics would be (high, medium or low) for the 5-year and 10-year time horizons. This assessment was then used during the development of the needs, challenges and potential solutions tables for each of the five enabling capabilities. Interestingly, flexibility (as currently defined as a metric) was not deemed something that the Roadmap Team would have any significant impact on, and there were other sub-areas of the other metrics that were assessed to be in a similar position. Table 2 is a summary of the main metrics that the Supply Partnership Management Roadmap Team assessed that had some impact that could be brought to bear over the 5–10-year time horizon. These should be considered when reading the needs, challenges and potential solutions for each of the five enabling capabilities.

Table 2: Roadmap Team impact on overall metrics – 5- and 10-year metrics for flexibility, speed, quality and cost

<table>
<thead>
<tr>
<th>Driver</th>
<th>Metric</th>
<th>Current state</th>
<th>5-year target</th>
<th>10-year target</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexibility</td>
<td>Facility utilization percentage</td>
<td>&lt;70%</td>
<td>&gt;85%</td>
<td>&gt;95%</td>
</tr>
<tr>
<td></td>
<td>Titer range in upstream that is directly accommodated by downstream facility fit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fed batch: 0.1–2gm/L</td>
<td>0.05–1gm/L/day</td>
<td>Fed batch: 1–10gm/L</td>
<td>Fed batch: 2–40gm/L</td>
</tr>
<tr>
<td></td>
<td>Perfusion: 0.5–5gm/L/day</td>
<td>Perfusion: 0.5–10gm/L/day</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Product change-over time for one production train</td>
<td>3 days</td>
<td>&lt;18 hours</td>
<td>&lt;8 hours</td>
</tr>
<tr>
<td></td>
<td>Time to reconfigure suite for new process</td>
<td>&gt;2 weeks</td>
<td>&lt;1 week</td>
<td>&lt;2 days</td>
</tr>
<tr>
<td></td>
<td>Number of platforms per suite (e.g. ability to change between CHO, E. coli, yeast, gene therapy within a suite)</td>
<td>1</td>
<td>3</td>
<td>&gt;5</td>
</tr>
<tr>
<td>Speed</td>
<td>Time to produce first GMP material for the clinic</td>
<td>18–24 months</td>
<td>12 months</td>
<td>8 months</td>
</tr>
<tr>
<td></td>
<td>Facility build speed</td>
<td>3 years</td>
<td>2 years</td>
<td>1 year</td>
</tr>
<tr>
<td></td>
<td>Speed to market</td>
<td>7–10 years</td>
<td>5 years</td>
<td>3 years</td>
</tr>
<tr>
<td></td>
<td>Time to make product (E2E speed)</td>
<td>4–6 months</td>
<td>2 months</td>
<td>1 month</td>
</tr>
<tr>
<td></td>
<td></td>
<td>100%</td>
<td>50% reduction</td>
<td>75% reduction</td>
</tr>
<tr>
<td></td>
<td>Time to release product (E2E speed)</td>
<td>4–12 weeks</td>
<td>2 weeks</td>
<td>1 day</td>
</tr>
<tr>
<td></td>
<td>Time to introduce a change to an existing process</td>
<td>6–12 months US/EU</td>
<td>2 months US/EU</td>
<td>1 month US/EU</td>
</tr>
<tr>
<td></td>
<td></td>
<td>18–24 months ROW</td>
<td>18 months ROW</td>
<td>6 months ROW</td>
</tr>
<tr>
<td>Quality</td>
<td>Cost of non-quality</td>
<td>&gt;10% of operating costs</td>
<td>10% of operating costs</td>
<td>2% of operating costs</td>
</tr>
<tr>
<td></td>
<td>Process variability (ppk)</td>
<td>&lt;1.2</td>
<td>&gt;1.5</td>
<td>&gt;1.8</td>
</tr>
<tr>
<td></td>
<td>Assay quality (ppk)</td>
<td>&lt;1.2</td>
<td>&gt;1.5</td>
<td>&gt;1.8</td>
</tr>
<tr>
<td></td>
<td>Inventory quantity</td>
<td>3–6 months</td>
<td>50% reduction</td>
<td>90% reduction</td>
</tr>
<tr>
<td></td>
<td>Inventory cover</td>
<td>2 months</td>
<td>2 weeks</td>
<td>2 weeks</td>
</tr>
<tr>
<td>Cost</td>
<td>Total cost to supply</td>
<td>$100/gm (mAbs)</td>
<td>$50/gm (mAbs)</td>
<td>$10/gm (mAbs)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(100%)</td>
<td>50% reduction</td>
<td>90% reduction</td>
</tr>
<tr>
<td></td>
<td>Cost of up-front investment in manufacturing</td>
<td>$500m+ DS facility (depends on capacity)</td>
<td>$100m DS facility</td>
<td>$50m DS facility</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$100m+ DP facility</td>
<td>$50m DP facility</td>
<td>$25m DP facility</td>
</tr>
<tr>
<td></td>
<td>Cost from Phase III process analytical and formulation development to launch</td>
<td>25% reduction</td>
<td>75% reduction</td>
<td></td>
</tr>
</tbody>
</table>
4.1 Openness and trust

4.1.1 Needs

“Think about this: if it’s 5pm on a Friday and you call your supplier, will they answer the phone? A great, empowered supplier will take your call (not because they fear you’ll can them if they don’t), but because they value the relationship and what you’re working on together.”

A truly effective relationship with a supplier requires that both parties acknowledge that a traditional buyer-seller relationship is not sufficient. For the results to be exceptional, there must be a higher level of openness and trust between the companies. This translates to sharing data and fostering an environment where both share the same objectives.

A critical element of openness is knowing that what is shared will not be used against the sharing party. This requires an up-front understanding regarding what each will do with the information and that the intention is to work together to solve issues. Each company will have their own interests but must work cooperatively to ensure constructive use of the data shared. Timeliness of the data is also important to enable a quick review and decisions based on real-time data.

In the early stages of discussions between the companies, openness and trust can be addressed by agreeing on the ‘rules of engagement’. This may include guidelines on what data is to be shared and the purposes for it, e.g. supply prioritization processes, product disposition, responsible parties and an escalation process. With these understood up-front, conflicts are minimized and openness and trust continue to be a critical element of the relationship. Once these guidelines have been discussed, the customer and supplier can work to develop joint objectives, agree key performance indicators and deliverables, and work towards the future roadmap together.

Although in a different industry, Cargill and J.M. Smucker’s have embraced the openness and trust concept with their New Ways of Working Together (NWWWT) initiative (developed by a group of companies, retailers and manufacturers, supported by technology providers and the Grocery Manufacturers Association of the USA and further developed by the Global Commerce Initiative). See Figure 1. They have achieved exceptional results in collaboration and innovation. Below are the elements they have formalized in the relationship:

- multiple points of contact
  - business team focus
- open exchange of information
- workspace
  - ‘ours and ours’
  - shared labs/staff/plants
- intellectual property
  - shared/dual use
  - joint value created
  - alignment
    - agreed to by all
    - honest evaluation
    - known value.

An environment of openness and trust is achievable but requires both customer and supplier to align on fundamental principles of commercial, quality and supply expectations. This often requires concessions by both parties. The benefit of this type of relationship is a more productive/efficient one when dealing with crisis, opportunity and long-term planning. This commitment to openness and trust must remain a top priority for both sides. As the common saying goes, “It takes years to build trust and moments to lose it”.

Collaboration

Once the relationship between customer and supplier has been recognized as a partnership, the interactions between them must become a collaboration, as each becomes an extension of the other’s capabilities.

“Build more trusted partnerships by sharing more and figuring out a way where both parties can have great deals that are mutually beneficial.”

Early engagement with R&D is key, resulting in a full alignment of future requirements, function specifications and identified opportunities for standardization. The parties should also address the IP expectations around ownership and right-to-use. Specifics such as validation process reviews and lifecycle plans should be discussed and agreed. There may also be incentives for each party and, conversely, required penalties.

Challenges exist in establishing these partnerships. They include concerns from the legal perspective, insistence on IP ownership and misalignment of goals. There may be a mismatch in the length of commitment expected from both sides. Less tangible concerns are cultural or geo-political issues and changing needs. Regardless of the challenges,

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3 NWWT presentation, Cargill and Smucker’s, October 2016. Used with permission.
the extent of openness and trust present in a relationship will help to find solutions to the challenges involved.

One effective way to facilitate close collaboration between companies is to co-locate teams in the same facility. This enables real-time interactions and exchanges and builds a team spirit. If that is not possible, face-to-face workshops or meetings bring a similar benefit around a focused topic. The ability to collaborate via tools that enable chats, share documents and track actions and progress will also be a significant contributor to the breakthrough potential of collaboration.

Collaboration is most effective when the parties can see and learn directly from the other. Often this requires a visit to each other’s facility to fully understand a process, its challenges and current capabilities. Each should know what information can be shared with their partner, while challenging each to provide as much as possible without breaching the required confidentiality guidelines.

Collaboration may also include joint talent development, meaning that both companies take part in developing people directly involved in the collaboration. This may involve assignments at the other’s facility, participating in cross-company training or offering mentoring/advice opportunities across the organizations.

“A leading consumer package goods company includes personnel from key suppliers in its cross-functional teams, encouraging input from specialists with deep skills in Engineering and Research and Development to improve the quality, efficiency, and differentiation of products.”

To summarize, future developments between customer and supplier should take a more collaborative approach, ensuring each brings their best to the activity. This requires that both look at the relationship in a different way and challenge the previous limitations of data-sharing and openness. Developing a high level of trust will bring optimal results to the partnership, achieving what neither company could have done on their own.

### Development

A supply partnership cannot simply start without some significant up-front activities. As with any relationship, this partnership must be developed into one that will bring the value expected by both parties.

Initially, a search must determine which suppliers have the capabilities to meet a need. Together with other considerations (e.g. financial health, strategic fit, performance history and interest) a mutual decision can be made on the willingness to partner.

The necessary follow-up would then include establishing parameters for the two companies to work together. This would likely include a master agreement, IP discussions and expectations and alignment on the trust and collaboration expected. Both parties must know what is expected of them, which must be agreed before a successful partnership can be formed.

We know that quality is defined as conformance to specifications; these agreements and expectations become the specifications against which the relationship will be judged. This also translates into the generation and review of specifications, processes and validations. Both partners must have an active part in the development of these deliverables. Allowances in project timing should be made to ensure this happens. Without both parties’ involvement, the result could likely miss the quality expectation, resulting in potential failure.

This development activity requires additional discipline and facilitation. This should come in the form of agreed milestones and scheduled reviews for each project. These ensure continued alignment of the partners and facilitate an open dialogue between the teams.

“A beverages company has worked with some of its key suppliers to tie the rewards of their sales teams to the jointly agreed performance scorecard, ensuring that buyers and suppliers have common incentives.”

Though the commitment to openness and trust must be a personal one from each participant, the development process must also ensure that each company can clearly communicate expectations and monitor the execution of the activities between the partners. See Table 3.

### Regulatory

The biopharmaceutical manufacturers and suppliers need to collaborate to make the regulatory process more efficient and streamlined. As regulatory expectations evolve, they often require an increased level of involvement from the supply base. Certain key elements are needed:

- supplier trusted data – comparable in content and quality to biomanufacturer-developed data packages
- standardized data packages to ease the evaluation of one supplier option to the next
- biomanufacturers need regulatory documents drafted carefully to include provision for plug-and-play with clear supplier accountability for quality while ensuring flexibility
- processes need to be characterized to allow multiple options for the process
- suppliers needs to have regulatory information readily available for inquiry from regulatory agencies.

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2 Ibid
There are a number of challenges to manage when attempting to address the collaboration need:

- suppliers’ quality management systems need to be developed
- biomanufacturer quality assurance needs to accept supplier-provided data and information
- regulators’ confirmation that supplier-derived test data is sufficient
- suppliers need to be willing to align on standardized formats/data sets
- biopharmaceutical manufacturing needs to balance speed to market pressures with ensuring regulatory documents are not being too restrictive when in commercial state.

There are a number of solutions to address the needs and challenges:

- industry training for suppliers – what to expect from regulatory agencies, such as standardized documentation
- biopharmaceutical leadership with regulatory agencies to drive for acceptance of supplier-derived test data (potentially through a third-party, e.g., BPOG or Parenteral Drug Association)
- audit and periodic recertification of supplier quality management systems, such as standardized criteria
- biopharmaceutical companies to include commercially oriented aspects into regulatory filing efforts
- suppliers use drug master file where appropriate to ensure regulatory needs are met.

Management

Biomanufacturers and supply partners require ‘rules of engagement’ that can be established to take the first step towards openness and trust. Examples include escalation processes, how shared data may be used, supply prioritization processes, product disposition, etc.

In addition, IP parameters and ownership should be defined at the start of projects.

It is sometimes difficult for biomanufacturers and supply partners to be proactive to set the right expectations. Parties often revert to reactive ‘crisis management’ mentalities, which can lead to ill will and the opposite of ‘openness and trust’. In addition:

- there are often potentially significant legal or liability implications as a result of supplier quality issues
- organizations may be pressured by short-term metrics and goals, losing site of the long-term needs.

There are a number of potential solutions that include:

- peer-to-peer management engagement at the beginning of commercial relationships to establish expectations at all levels of organizations
- establishing risk-sharing between biomanufacturers and supply partners, i.e., some ‘skin in the game’ from both sides
- leveraging a robust agreement process to establish the right expectations up front.
Figure 1: Push along the maturity curve

NWWT is a force multiplier

Current state
- Lower impact
  1. Cargill current offers, pushes ideas
  2. Project list – reactionary vs. proactive
  3. Good quality/service
  4. Transactional point to point communication

Evolution
- Pushing current innovations - closing
  1. Near term project planning – tactical
  2. Tolling arrangement for tolling/hydro
  3. Unique pricing models
  4. Proactive discussion on investments to meet JMS needs
  5. Pursue solutions to solve common issues

Revolution
- Joint development - pulling/connecting
  1. Joint planning and strategy sharing
  2. Joint IP concepts
  3. Joint value creation one voice to each other
  4. Sharing ALL pertinent information

Value added:
- Low
  1. Cargill current offers, pushes ideas
  2. Project list – reactionary vs. proactive
  3. Good quality/service
  4. Transactional point to point communication
- Medium
- High

Commitment
- Low
- Medium
- Higher
- Highest

Notes:
7 NWWT presentation, Cargill and Smucker's, October 2016. Used with permission.
4.1.2
The needs, challenges and potential solutions

Table 3: Openness and trust – needs, challenges and potential solutions

<table>
<thead>
<tr>
<th>Needs</th>
<th>Collaboration:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• suppliers as an extension of the biomanufacturer</td>
</tr>
<tr>
<td></td>
<td>• engagement with R&amp;D teams early in the process to enable standardization of technology platform</td>
</tr>
<tr>
<td></td>
<td>• set clear technical and functional expectations and develop collaborations</td>
</tr>
<tr>
<td></td>
<td>• end-user functional requirements defined well and shared with supply partners</td>
</tr>
<tr>
<td></td>
<td>• agreements need to be aligned with project lifecycle and incentivized for both parties</td>
</tr>
<tr>
<td></td>
<td>• co-owned design and validation packages for novel solutions</td>
</tr>
<tr>
<td></td>
<td>• IP parameters and ownership defined at the start of projects.</td>
</tr>
<tr>
<td>Challenges</td>
<td>legal</td>
</tr>
<tr>
<td></td>
<td>IP ownership</td>
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<tr>
<td></td>
<td>commitment horizons</td>
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<td></td>
<td>cultural issues</td>
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<tr>
<td></td>
<td>geopolitical</td>
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<tr>
<td></td>
<td>circumstances change – need goes away</td>
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<tr>
<td></td>
<td>break of trust – integrity.</td>
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<tr>
<td>Potential solutions</td>
<td>co-locate selected teams</td>
</tr>
<tr>
<td></td>
<td>define the type of information</td>
</tr>
<tr>
<td></td>
<td>create an industry demand picture of raw materials and equipment</td>
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<td></td>
<td>visit each site and explain the process</td>
</tr>
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<td></td>
<td>biomanufacturers share industry pipeline information</td>
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<td></td>
<td>joint talent development program(s)</td>
</tr>
<tr>
<td></td>
<td>real-time data sharing</td>
</tr>
<tr>
<td></td>
<td>leadership – to agree buy-in and IP</td>
</tr>
<tr>
<td></td>
<td>up-front workspace framework – to define IP boundaries</td>
</tr>
<tr>
<td></td>
<td>focus on technical goals – have the right quality of people to set technical requirements and agree commercials</td>
</tr>
<tr>
<td></td>
<td>mediation system required for when collaboration ‘breaks’.</td>
</tr>
</tbody>
</table>

MRL

<table>
<thead>
<tr>
<th>Needs</th>
<th>Development:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• transparency of technologies and capabilities between biomanufacturer and supply partner</td>
</tr>
<tr>
<td></td>
<td>• shared objectives – guided development with milestone incentives</td>
</tr>
<tr>
<td></td>
<td>• mutually agreed functional specifications</td>
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<td></td>
<td>• functionally based design and harmonized with industry standards.</td>
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<tr>
<td>Challenges</td>
<td>understanding functional specifications</td>
</tr>
<tr>
<td></td>
<td>certificate of assurance is not always predictive of functional performance.</td>
</tr>
<tr>
<td>Potential solutions</td>
<td>create ‘rules of engagement’, including escalation processes, data security, supply prioritization, product disposition, etc.</td>
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<tr>
<td></td>
<td>integrated risk management processes</td>
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<tr>
<td></td>
<td>non-routine engagement, e.g. supplier/manufacturer co-educational days</td>
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<tr>
<td></td>
<td>supplier operational control limits (used to set specification limits).</td>
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</table>

<table>
<thead>
<tr>
<th>MRL</th>
<th>IP – Intellectual property, MRL – manufacturing readiness level</th>
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<tbody>
<tr>
<td></td>
<td>Potential solutions manufacturing readiness level</td>
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</tbody>
</table>

Research  Development  Production
### Table 3: Openness and trust – needs, challenges and potential solutions (continued)

<table>
<thead>
<tr>
<th>Needs</th>
<th>Regulatory:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• process characterization and supplier controls to allow multiple options for process</td>
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<td></td>
<td>• supplier trusted data – comparable in content and quality to users’ internally developed data packages</td>
</tr>
<tr>
<td></td>
<td>• provision for plug-and-play with accountability of supplier for quality (additive manufacturing environment).</td>
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</table>

| Challenges | |
|------------| |
|           | • end-users’ quality assurance need to buy into need |
|           | • supplier quality management system needs to be developed enough to support |
|           | • regulators’ confirmation that supplier-derived test data is sufficient. |

| Potential solutions | |
|---------------------| |
|                     | • industry training for suppliers |
|                     | • leadership – drives for acceptance of supplier-derived test data |
|                     | • audit and periodic re-verification. |

| MRL | |
|-----| |

<table>
<thead>
<tr>
<th>Needs</th>
<th>Management:</th>
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<tbody>
<tr>
<td></td>
<td>• IP parameters and ownership defined at start of projects</td>
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<tr>
<td></td>
<td>• change management programs between supply partners</td>
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<td></td>
<td>• ship to stock; reduced inspection</td>
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<td></td>
<td>• mutual secondment schemes.</td>
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| Challenges | |
|------------| |
|           | • legal responsibility, accountability and IP ownership |
|           | • lack of planning and scope-setting. |

| Potential solutions | |
|---------------------| |
|                     | • development of partnership initiatives |
|                     | • joint ownership and understanding of the supply chain. |

| MRL | |
|-----| |

IP – Intellectual property, MRL – manufacturing readiness level
4.2 Standardization

Standardization is crucial for the roadmap visionary goal to simplify, reduce cost and improve efficiency for the biomanufacturing industry. Standardization will enable greater flexibility and agility of biomanufacturing processes. However, the vision is to drive standardization where it is meaningful and applicable while supporting innovation. At the same time, standards should drive competition instead of creating entry barriers for supply partners.

Another challenge is how to standardize as an industry. This section highlights the value of standards and suggests a future perspective of where and how to set standards. As an example, consider the areas where standardization could have an impact on the disposables and single-use systems.

There needs to be a major focus on standardization in disposables design, including connectors, manifolds, tubing and bags. One could imagine developing standard designs with functional specifications that multiple suppliers could all comply with to drive more value through standardization and offering security of supply with multiple suppliers. A related idea is to create standards for individualized components of the disposables systems so that manufacturers have multiple vendor choices for sourcing the sub-components, and then can put together necessary bag/filter/tubing/manifold combinations as needed per the instructions in the batch documentation. This creates multiple benefits, such as standardizing the components to make them a commodity, (which decreases costs while ensuring a secure source of supply) decreasing lead times and decreasing supplier-related quality defects that can arise with highly customized systems. Table 4 indicates the needs, challenges and potential solutions for standardization.

4.2.1 Needs

Areas where standardization is needed are:

- in-line monitoring and real-time release – multivariate and single-use sensors
- modular and mobile – room design and connectors, process equipment capabilities, factory acceptance test/site acceptance test protocols, automation, room validation and facility control
- automated facilities – aligned standards and specifications for equipment (e.g. pre-packed columns) and integrity monitoring and multivariate sensors for predictive models, leading to the development of the ‘autopilot facility’ concept
- process technologies – help to build the value proposition for identified standardization across agreed raw materials and technologies.

Areas to be standardized are:

- approach to setting acceptable quality limits
- change control
- traceability
- classification
- supplier scorecards
- specifications for commodity-type materials – guideline creation
- alignment of test methods, e.g. quality control testing, release, etc.
- alignment of specifications
- industry-wide agreement of specifications for common commodities
- alignment of specification/standardization on:
  - primary packaging and quality
  - process analytics technology
  - sensor
  - films
  - connectors
  - leachables and extractables
  - common language for control (integration of modules from different vendors)
- recyclable raw materials
- industry data sharing for raw material tests
- standardize on CQAs. EDE of process data and linkage to CQAs of drug substance.

Execution and value of standardization

Achieving industry consensus for standards:

- industry consortium to drive standardization: ASTM, American Society of Mechanical Engineers, Parenteral Drug Association, United States Pharmacopeia, BPOG, Bio-Process Systems Alliance
- publications by consortia
- published industry material specifications
- standardized data requirements
- information standard rating system
- evaluate the potential of creating a consortium with other industry third-party organizations.
## 4.2.2
The needs, challenges and potential solutions

<table>
<thead>
<tr>
<th>Table 4: Standardization – needs, challenges and potential solutions</th>
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<td><strong>Potential solutions</strong></td>
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**MRL**

| MRL – manufacturing readiness level |  |
| **Potential solutions manufacturing readiness level** | **Research** | **Development** | **Production** |  |
4.3 Electronic data exchange and supplier integration

Current lead times in the biopharmaceutical industry are too long and the supply chain is too fragmented, complex and its management is ‘re-active’. A key vision for a shortened, integrated supply chain is the ultimate move towards ‘proactive’ supply management. A prerequisite for such a vision is to integrate the systems of supply partners and manufacturers via EDE and systems integration. This section highlights the long-term vision by leading biomanufacturers and their supply partners and exemplifies the value of EDE.

Electronic data exchange is one of the key opportunities in the biopharmaceutical industry to improve the efficiency and robustness of the manufacturing processes through an improved understanding of how variation in the raw material supply chain can impact on the manufacturing process. By gaining this knowledge, mechanistic models of this impact and the corresponding mitigation activities can be implemented to increase the robustness and reliability of the manufacturing network.

"Integration of business systems between Suppliers and Manufacturers must be progressed as an underpinning feature of a closer, long term, partnering arrangement between Suppliers and Manufacturers."79

To seize this opportunity, standardized protocols for EDE need to be created and adopted by the industry to reduce the cost of implementation by sharing the costs of development of the EDE platform across multiple end-users. This also eliminates differentiation by suppliers in the data provided and results in supplier-specific data transformation platforms at end-users. The point of differentiation by suppliers is the quantity and quality of data provided to end-users and how the data can be applied to reduce manufacturing variation. These efforts to create a sustainable process for EDE are currently being implemented through the creation of an ASTM standard for EDE that will be made public. The ASTM standard will be a consensus from the biopharmaceutical industry and will serve as a framework for establishing regulatory expectations on the quantity and quality of data exchange between suppliers and end-users.

4.3.1 Technical electronic data exchange – quality, in process

The electronic raw material data needs to be structured in a format that allows it to be associated with the manufacturing steps that use a specific raw material lot(s). This requires that the raw material data is associated with a unique ‘key’, which is specific to that lot of raw material from a specific supplier. That key can then be tracked in the manufacturing process to determine each manufacturing process step that used that unique raw material (technology such as Blockchain may have a role to play here within the supply chain). This genealogy map of raw materials to the process also needs to document the proportionality of the raw material that was used in each manufacturing step to determine the significance of the presence of a specific raw material lot to the process outputs. Supplier data needs to be structured to enable the functionality of these end-user genealogy tools to model raw material impact to process outputs.

This data exchange can be implemented in a staged process:

- **Stage 1**: Electronic exchange of existing data that is currently provided as paper or a ‘flat’ digital file
- **Stage 2**: Exchange of primary supplier (N) manufacturing data, including critical process controls and raw material lots
- **Stage 3**: Exchange of supplier and sub-supplier (N-1) data, including raw material certificates of assurance and sub-supplier critical process controls.

The objective of these stages is to leverage existing data sources initially to establish the sustainable and standardized processes of EDE between suppliers and end-users in a format that can be imported into a searchable database (e.g. not a flat pdf file). Once this sustainable process is established, the data collection can be expanded and still linked to the same unique identifier for a specific raw material lot. This system can be expanded as additional sub-suppliers in the supply chain network are incorporated into the EDE program.

4.3.2 Supply planning electronic data exchange

Electronic data exchange is essential for improved accuracy in demand planning. In an ideal scenario, the supplier has visibility of real-time changes in customer demand. Integration of enterprise resource planning systems will assist in reducing lead times with ‘real-time’ material availability and automatic replenishment actions based on ‘trigger’ stock levels with fully automated inventory management systems.

There are ongoing initiatives and collaborative work involving cloud service providers and other web-based interfaces to facilitate data interchange. These are currently being evaluated and/or implemented across several major biopharmaceutical companies. An example is a company in Japan that has already transferred more than 40% of the data from its physical data centers to its third-party cloud services provider.
A schematic example of supply chain transparency facilitated by the cloud is shown in Figure 2.

Figure 2: Cloud-hosted supply chain

This increase in data exchange throughout the supply chain will require greater transparency of both the suppliers and the end-users. Suppliers and end-users need to have a structured and transparent format to review the data to ensure a mutual understanding of the impact on the overall supply chain and manufacturing network before implementing mitigating activities. These mitigation activities must be implemented with achieving the lowest total cost of ownership for the entire manufacturing and supply chain network and should result in a partnership to share the mitigation costs throughout the supply chain. If these ways of working in this new environment are agreed and adhered to, then biopharmaceutical suppliers and end-users have the potential to significantly improve the reliability of the biopharmaceutical supplier network and, ultimately, the reliability of the therapeutic supply to their patients.

Supplier integration does not need to stop at the integration of EDE systems. For a shorter, more robust and integrated supply chain the view could be that personnel from differing functions – particularly those that are supply chain-related – should be seconded and exchanged between companies with investments made. A start has been made with cross-training, but this is a significant opportunity in the integration journey between manufacturers and suppliers.
4.3.3 Needs
The following highlights the long-term vision by leading biomanufacturers and their supply partners and exemplifies the value of EDE.

Long-term EDE and supplier integration vision statements
These examples have been extracted from interviews with senior executives from biomanufacturers and supply partners, which were conducted to gain an insight and direction for the Supply Partnership Management report. These examples highlight the importance of EDE and supplier integration for senior executives.

"Integration of business systems between Suppliers and Manufacturers must be progressed as an underpinning feature of a closer, long term, partnering arrangement between Suppliers and Manufacturers that is founded on openness and trust and with shared understanding of business needs with visibility of business plans and objectives as an ideal...”

"Suppliers having real time visibility of demand enabling them to create a forecast themselves...”

"Integration of business systems between Suppliers and Manufacturers and sharing of data will assist in developing a shared understanding that will aid confidence, embed quality as a material supply feature to aid qualification, reduce ongoing testing requirements and shorten both supply and production as material is incorporated more rapidly into the manufacturing process..." Biomanufacturing company A

"An increasing need for integration between Biopharmaceutical Manufacturers and Suppliers and a key feature of a future Supply Chain over the next ten years with the example of our company’s ongoing initiatives and collaborative work involving SAP and other web based interfaces...”

"Recognition that current internal controls and data accuracy is a challenge with significant ongoing efforts to improve both and the goal of more effective control and improved data accuracy key features in moving the Industry forward to meet the challenges ahead...” Biomanufacturing company B

“We have started some collaborative planning initiatives with key suppliers... There is a need to improve visibility between Suppliers and Manufacturers across all aspects as an example between forecasting and capacity, to improve the whole Supply Chain.” Biomanufacturing company C

Value of establishing electronic data interchange between suppliers and manufacturers

Today, there are mature systems for EDE to exchange information about the supply chain, e.g. forecasting and planning. These allow for the integration of the lean and agile manufacturing paradigms in the total supply chain and for modeling the agility of the supply chain. The data from which can be used to reduce the total cycle time and increase the agility of the supply chain. These are highly desirable outcomes from the use of EDE that the biopharmaceutical industry has yet to fully take advantage of.

Other areas where EDE can be impactful include the management of quality control data and technical data between supply partners, along with manufacturing process-derived control data to drive continuous improvement and process analytical technology approaches. See Table 5 for needs, challenges and potential solutions.

13 Mason-Jones R and Towill DR, Total cycle time compression and the agile supply chain, International Journal of Production Economics, 1999
4.3.4
The needs, challenges and potential solutions

Table 5: Electronic data exchange and supplier integration – needs, challenges and potential solutions

<table>
<thead>
<tr>
<th>Need</th>
<th>Electronic data exchange – supplier integration:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• common EDE standard for suppliers and end-users</td>
</tr>
<tr>
<td></td>
<td>• common practice for secure self-serve data exchange portal for supplier and end-user provided data (e.g. change notifications, certificates of assurance, etc.)</td>
</tr>
<tr>
<td></td>
<td>• common practice that customer demand will drive supplier manufacturing schedule in real-time via EDE</td>
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<tr>
<td></td>
<td>• move to standards for data exchange, e.g. ASTM guidelines as defined in WK51651</td>
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<tr>
<td></td>
<td>• define process performance data that qualifies the impact of raw material on end-users’ CQAs to provide as feedback to supplier.</td>
</tr>
</tbody>
</table>

| Challenges | • lack of capability for full supplier integration  |
|            | • concerns over security and IP ownership           |
|            | • not all data exists in a digital format           |
|            | • quality assurance review of digital data          |
|            | • no common standard                                |

| Potential solutions | • in-house supplier innovation programs  |
|                     | • legal framework to allow EDE and supplier integration |
|                     | • development of a common standard.               |

MRL – manufacturing readiness level

<table>
<thead>
<tr>
<th>MRL</th>
<th>Potential solutions manufacturing readiness level</th>
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<tbody>
<tr>
<td></td>
<td>Research</td>
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</table>

4.4 Quality built-in

4.4.1 Needs

When we think of quality built-in, we tend to think of lean manufacturing. The goal is to have quality built into your processes as much as possible. We also think of ‘jidoka’, which highlights the causes of problems that leads to improvements in the process to build in quality. How do we associate quality built-in with our supplier partners? As the industry continues to develop relationships with our suppliers, it will become imperative that it works collaboratively to ensure we receive the highest quality product. The industry needs to help supplier partners understand the criticality of their role in providing high-quality medicines to patients. Table 6 lists needs, challenges, and potential solutions.

A critical element of quality built-in is ensuring there are clear quality expectations and agreements. This requires both the company and the supplier to engage in a constructive dialogue to make certain there are no surprises upon receipt of materials. This will help suppliers to consistently produce materials that meet the expectation of the companies they support. Suppliers need to work with the industry to move beyond just meeting the specification and drive toward continuous process verification, which should feed the risk assessment for the material. This approach will support increased collaboration between suppliers and industry to ensure the highest quality materials are being provided.

Suppliers and industry need to work together towards building quality in at the source. Suppliers need to develop reliable processes that will yield consistent results and drive towards zero defects. The ‘zero defects’ approach is a management tool aimed at reducing defects through prevention. It is directed at motivating people to prevent mistakes by developing a constant, conscious desire to do their job right first time. One method to achieve this goal is to instill practical, problem-solving techniques to help correctly identify the root cause of any defects. Suppliers will also need to set up monitoring systems to ensure the actions taken are effective. This will help suppliers implement the appropriate corrective and preventative actions to continue the drive towards zero defects.

14 http://www.toyota-global.com/company/vision_philosophy/toyota_production_system/jidoka.html
When biomanufacturers talk about driving a continuous improvement culture at our suppliers, we need to provide a framework to them as to how to develop this culture. One way to drive this culture is through metrics established by industry and suppliers working together. Another element in developing this culture is adopting a ‘right first time’ mentality at our suppliers. While this may sound like a cliché, it is a key element to ensure the highest quality material is being delivered to the industry.

Suppliers also need to understand and adopt the concept of ‘first pass yield’. This is calculated from the yields of each process without re-work (i.e. dividing the units entering the process minus the defective units by the total number of units entering the process). ‘First pass yield’ does not take re-work into consideration. This concept will help suppliers determine what improvements are required to allow for a compliant and efficient receipt and release process at the end-user’s location.

Another area to develop is a quality framework across suppliers and manufacturers. We need to determine the important aspects of quality management. When we think of quality management, our goal is to achieve and maintain high-quality output. Suppliers need to emphasize quality performance in their analysis. This requires top management support to create an environment in which quality management activities are rewarded.

Suppliers need to focus on the reliability of supply. One way to ensure a high-quality supply is through risk reduction. Suppliers need to reduce the frequency and/or severity of losses to help the industry maintain the supply of key materials. One specific approach to enable this is to have a multi-tier visibility program in place, requiring suppliers to know the source risk of their own suppliers and the multiple tiers below. This full-scale knowledge will drive quality into the entire supply chain. Suppliers need to drive quality to the shop floor. In summary:

- biomanufacturers and supply partners need to establish clear quality expectations and agreements
- suppliers must consistently produce materials that meet industry expectations
- suppliers and customers need to adopt and practice lean principles
- suppliers need to build quality in at the source
  - reliable processes yield good results, such as standardized work
  - instill practical problem solving to identify the root cause of deviations
  - implement appropriate corrective and preventative actions
  - suppliers understand their importance in providing high-quality medicines to patients
- drive suppliers towards ‘zero defects’
- utilize metrics to drive a continuous improvement culture.
### 4.4.2
The needs, challenges and potential solutions

<table>
<thead>
<tr>
<th>Table 6: Quality built-in – needs, challenges and potential solutions</th>
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<tbody>
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<td><strong>Need</strong></td>
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<td><strong>Challenges</strong></td>
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<td><strong>Challenges</strong></td>
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<td><strong>Potential solutions</strong></td>
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<td><strong>MRL</strong></td>
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4.5 Forecast and inventory planning

At the higher industry level, we need to know there is a supply chain capable of providing consumables. Time investment is needed now, for example, in plastics, cell culture components and sources, critical services (e.g. sterilization, lyophilization), validation and engineering. At the individual company and local site level, improvements in collaborative planning, forecasting and replenishment are needed. For mobile scenarios, production support in local environments must be anticipated. Global standards are required for key raw materials and distribution of suppliers in local markets capable of delivering to those standards.

4.5.1 Needs

Needs, challenges, and potential solutions for Forecast and Inventory Planning are presented in Table 7. The top needs are as follows:

- identify sources of forecast variability and apply probability principles to forecast accuracy
- drive costs of highly variable demand levels impacting on costs with safety stock and expired materials
- develop supplier-managed inventory models to reduce lead times.

4.5.2 The needs, challenges and potential solutions

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<tr>
<th>Need</th>
<th>Forecasting and demand planning:</th>
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<tr>
<td></td>
<td>• transparency to capacity planning at the supplier (tiers 1 and 2)</td>
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<td>• transparency to long- and short-term demand for biomanufacturers – cross industry</td>
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<td>• utilize EDE for real-time planning</td>
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<td></td>
<td>• industry supply chain risk analysis and harmonized mitigation strategies</td>
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<td>• shared business continuity planning for key supply chain constraints and risks.</td>
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<th>Challenges</th>
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<td></td>
<td>• inherent variability in product development</td>
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<td>• visibility of gross-level raw material availability to the biopharmaceutical industry</td>
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<td>• visibility of gross-level key services (e.g. sterilization) availability to the biopharmaceutical industry</td>
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<td>• visibility of the sub-tier supply chain.</td>
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<th>Potential solutions</th>
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<td></td>
<td>• external reports – defined for biomanufacturer industry needs that are specific to support the Technology Roadmap metrics (5–10–year horizon)</td>
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<td>• supply chain mapping of service providers</td>
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<td>• utilization of platform raw materials for diverse product development programs</td>
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<td>• creation of category-specific user groups to build cross-industry vigilance.</td>
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<th>MRL – manufacturing readiness level</th>
<th>Potential solutions manufacturing readiness level</th>
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<td>Research Development Production</td>
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</table>

Table 7: Forecast and inventory planning – needs, challenges and potential solutions
5.0 Linkages to other roadmap teams

Supply partnership management is embedded in each of the roadmap reports, making valuable contributions to the long-term vision of the overall supply chain and at the individual roadmap level. Their perspectives are included from those individual reports:

5.1 In-line Monitoring and Real-time Release

Supply Partnership Management team perspectives:
- systems integration between supplier and customer
  - on-line monitoring of raw materials, linking raw material performance impact on CQAs in drug product and drug substance
  - development of biologics drug substance relevant predictive models
  - supply chain genealogy
- specification alignment across the industry
  - supplier to focus on multivariable and single-use technology (SUT) sensors.

In-line Monitoring and Real-time Release Roadmap perspectives

5.2 Modular and Mobile

Supply Partnership Management team perspectives:
- develop standards for room design and connectors, process equipment capabilities, factory acceptance test/site acceptance test protocols, automation, room validation and facility control
- provide infrastructure and supply chain to enable mobile manufacturing scenarios
  - hub and spoke supply chain, as in the leading online retail order fulfillment models
  - ‘just in time’ or vendor-managed inventory and other novel supplier arrangements
- co-location with suppliers
- equipment leasing.

Modular and Mobile perspectives

5.3 Knowledge Management

Supply Partnership Management team perspectives:
- work with the supplier on the compatibility of IT systems to enable easy transfer of data
  - IT systems integration, third-party knowledge management: including predictive controls of raw materials and shared network (internal and external)
  - EDE of process data and linkage to CQAs of drug substance
  - change notification in process of supplier (monitoring and tracking of vendor-initiated changes)
- protect IP
  - knowledge is part of the contract
  - investigate opportunities for progressive sourcing platforms such as crowdsourcing.\textsuperscript{15, 16, 17, 18}

Knowledge Management perspectives

5.4 Automated Facility

Supply Partnership Management team perspectives:
- align standards for biomanufacturing equipment and raw materials
  - standardization and full integration across supplier systems
  - pre-packed columns integrity monitoring
- specification alignment across the industry
  - as in In-line Monitoring: inquiry for multivariate sensors and development of predictive models/’autopilot facility’.

Automated Facility perspectives

5.5 Process Technologies

Supply Partnership Management team perspectives:
- helping to build the value proposition for suppliers for driving standardization for the following raw materials/technologies:
  - cell separation for high-density processes
  - high-capacity resins
  - alternative affinity ligand
  - pre-packed columns
  - improved membrane technology
  - virus filtration (absolute)
  - buffer optimization: pre-formulated tablets
  - solubilization technologies
  - bioburden and adventitious viral agents (AVA) control from the source of raw material
  - dust-reduction technologies.

Process Technologies perspectives

\textsuperscript{15} A Wexler MN, Reconfiguring the sociology of the crowd: exploring crowdsourcing, International Journal of Sociology and Social Policy, 2011, Vol. 31 Iss ½ pp. 6–20s
\textsuperscript{16} Innovating with the in-crowd: Crowdsourcing is part of an honorable tradition, Strategic Direction, Vol. 29 Iss 8 pp. 9-12 (2013)
\textsuperscript{17} Exploring crowdsourcing: a viable solution towards achieving rapid and qualitative tasks, Library HiTech News, Vol. 30 Iss 2 pp (2013), 14-20 http://dx.doi.org/10.1108/LHTN-01-2013-0002
\textsuperscript{18} Crowdsourcing: divide the work and share the success, Library HiTech News, Vol. 30 Iss 4 pp. 1-5 (2013) http://dx.doi.org/10.1108/LHTN-03-2013-0017
5.6 Other industry initiatives

Within BPOG, there are several linkages:

Drug substance:

Raw materials variability has been a subject of interest from a supplier perspective for the Drug Substance workstream and a document entitled *Patient-centric requirements for the supply of raw materials into biopharmaceutical manufacturing* has already been published and is available through BPOG. Other areas of interest in drug substance are:

- raw materials variability
  - supplier change notification
  - supplier technical questionnaire aligned with the ‘RX360’ supplier questionnaire activity
  - future work with cell culture media, looking at variability within components
- disposables.

Fill finish:

- stopper quality
- auto-injector design and manufacture.

BioPhorum Information Technology group (BPIT):

As part of this group’s work to develop a Digital Plant Maturity Model, there is ongoing activity around EDE, including interest in:

- Allotrope Foundation – Ontology
- ExxonMobil: Open architecture for data exchange (The Open Group).

BPOG Supply Partner Phorum:

- regulator engagement through supply partner engagement with the BPOG Regulatory Interaction Group
- supply chain mapping
- forecasting and demand planning
- business continuity framework
- communication and data exchange formats.

6.0 Emerging and/or disruptive technologies

Introduction

The preceding dialogue on supply partnership management assumes a known level of technology and acknowledges the best practices derived from what is known today but which may not be in use in the biopharmaceutical industry as common practice. But what new technologies will exist in the future? What will we need to be prepared for as we look ahead? Emerging and/or disruptive technologies will provide the next generation of advances. We will comment on the coming trends and what to consider as these become more available and, ultimately, mainstream. It is important to note that these are not endorsements for any particular technology as many are unproven, risky or even irrelevant.

The options for the upstream side of the business (the interaction of raw materials and services, rather than drug product) that will impact supply partnerships include business tools, communication, data management and approaches. New technologies being addressed in other areas, such as process technologies or drug development tools, require procurement’s integral involvement, but will not be addressed in this section, which addresses the functional aspects of supplier partnerships.

What will these technologies provide?

Why do we continually need advancements within supplier partnership management? There is a need for quicker feedback and better data to make better decisions. Also, the link to specifications and the supplier’s capability is clearly important and is dependent on good data.

We have recognized the need for closer collaboration between companies, driving the organizations to work together for better results. This collaboration can also lead to significant innovations in product and process. This collaboration should also include the ability for each partner’s data to be understood by the others, requiring that the data and systems should be able to communicate without extensive intervention by personnel. A standard language or protocol would facilitate the desired seamless interaction.

Ongoing pressure for both companies to reduce costs and eliminate non-value-added activities also begs for more efficient ways of working with suppliers, automating processes and reducing the resources required to manage the relationship. The right tools can also provide a better understanding of the total cost of ownership, helping to address cost concerns and find solutions to ensure competitiveness.
Quality built-in
At the forefront of advancements, any technology that can improve quality and the end-product to our consumers, will be of paramount interest. In this area, access and sharing of real-time data, raw material, in-process and final inspection data will allow the parties to address issues more quickly and effectively. Access to raw material data will provide customers with the assurance they need to know that the product meets the quality requirements. Additionally, the availability of electronic records is an advancement that will continue as a benefit to the customer and supplier. Paperwork errors, timeliness of receipt and the ability to access the records quickly are all benefits of electronic records.

Each of these is likely to be included in a purchased quality management system tool, offering cloud-based data, change and document management, and compliance-assurance programs.

Technology platforms
New technologies offer breakthrough potential. Some are already well established, such as EDE and minimize set-up, are cloud-based and reduce validation effort. Often these do not require the purchase or installation of software.

“The processing of information, said Rosenberg, also includes task management and fulfillment reports that allow buyers to work with suppliers with insight into tasks that must be completed as orders are completed. That could, for example, include digital signatures on documents [for, say, compliance purposes].”

Big Data and the Internet of Things offer access and analysis of large amounts of data for decision making, predictive analytics and optimization of processes based on materials and risk management. The possibilities are limitless for the future of information and only bounded by the availability and security of the data we desire.

“The amount of digital data is doubling every two years and by the year 2020, about 1.7 megabytes of new information will be created per person every second (Source: IBM). Although existing digital data is estimated to be over 4.4 zettabytes, only 0.6% of that data is currently analyzed. Increasingly sophisticated systems for data analysis are driving attempts to better interpret information, with significant financial benefits underlining a continued interest among procurement executives, as our survey highlights. Baseline magazine estimates that just a 10% increase in data accessibility will result in more than $66m additional net income for the average Fortune 1000 company.”

Blockchain technology has the potential to streamline transactions, improve the security of interchanges, eliminate non-value-added processing parties and simplify supply chain mapping. This also provides traceability to approved materials, proof of supply chain and optimization of the supply with the potential of customizing supply for output.

All these technologies also come with an expectation that they are accessible from mobile devices. The mobile mandate will extend to every aspect of our businesses and must play an integral part of our solutions. This includes application development, ease of use, simplification and data security.

Advances in traceability are already an important piece of our technological solutions. Utilization of GPS, RFID, sensors, 2D and 3D barcoding, among others, provide a more robust means of capturing data, managing inventories and establishing traceability. Paperless exchanges are also now possible and include shipping, labels, certificates of assurance and packing slips. Information availability and the establishment of standards to communicate between companies must be the focus to keep up with these advances.

The development of 3D printing technology will also have drastic implications in numerous industries, aside from the traditional plastics prototyping. Advanced materials and precise capabilities will expand the technology into metals, food processing and potentially pharmaceuticals.

“Digital-to-physical transfer. Local Motors builds cars almost entirely through 3-D printing, with a design crowdsourced from an online community. It can build a new model from scratch in a year, far less than the industry average of six. Vauxhall and GM, among others, still bend a lot of metal, but also use 3-D printing and rapid prototyping to minimize their time to market.”

Although the technologies have been in place for some time, supplier qualification, e-sourcing and RFx processes must also be improved, providing a more uniform approach.

On a broader scale, Industry 4.0 and all that is associated with it, will impact both suppliers and customers. Automation, lights-out facilities, elimination of personnel, driverless delivery, machines communicating between themselves, restocking and materials demand could be revolutionized by these trends. See Figure 3 for McKinsey & Company’s Industry 4.0 Levers Diagram, which highlights the potential applications and the impact of each to operations and the supply chain.

19 Communicating, Via Cloud, Across the Supply Chain, PYMNTS.com, 12/14/16
20 Johnston A., Procurement and technology: a vision of the future, Procurement Leaders, 2016
Figure 3: McKinsey & Company’s Industry 4.0 Levers Diagram

Industry 4.0 levers

- Virtually guided self-service
- Smart energy consumption
- Intelligent lots
- Real-time yield optimization
- Routing flexibility
- Machine flexibility
- Predictive maintenance
- Augmented reality for MRO
- Human-robot collaboration
- Remote monitoring and control
- Automation of knowledge work
- Digital performance management
- In situ 3-D printing
- Automation of supply chain optimization
- Batch size
- Real-time supply chain optimization
- In situ 3-D printing
- Automation of knowledge work
- Digital performance management
- In situ 3-D printing

Value drivers

- Service/after-sales
- Resource/process
- Asset utilization
- Labor
- Inventories
- Quality
- Supply/demand match
- Time to market

*Maintenance, repair and operations

McKinsey and Company

Partnership development
Within the biopharmaceutical manufacturer/supplier relationship, there are emerging technologies that will bring value to each party. Platforms for collaboration will continue to develop, further improving the innovation process and joint developments. Tools providing crowdsourcing and ‘chat’ capabilities will expand to impact more of the interactions between partners. Third-party providers and outsourcing partners will also likely expect full integration into supply chain through to raw materials. Tools should enable open data sharing into various parts of the supply chain.

How to adopt these technologies
What is the best way to take advantage of the next breakthroughs in the supply chain? First, there must be support for being innovative and progressive within the organization. The partners must also acknowledge their role in helping each other succeed in the leadership role. Usually, there is appreciable investment required, which must be budgeted and allocated to these activities. This investment may require the use of alternative cost models, as the previous way of calculating costs may become obsolete with these emerging processes.

As individual organizations are not typically experts in each of these emerging technologies, external input (e.g. consulting or academia engagement) could benefit a company looking to deploy the disruptive technologies. Once in the process, organizations would benefit from an iterative and agile methodology for proving the concept and deploying the changes in stages or pilots. Definition of cross-industry rules of engagement will ensure the parties’ expectations are clear. The criteria for success must also be defined and may need to distinguish between marginal gains and step gains.

Above all, change management is the key to success in implementing these emerging and disruptive technologies. Utilizing forums such as BPOG can assist organizations in taking advantage of these advances and furthering the supplier partnership.

7.0 Regulatory considerations
Specific considerations involving regulators and their agencies
The biopharmaceutical industry is a heavily regulated environment, with numerous agencies around the world that regulate activities in the industry. As our industry becomes ever more global, there has been an increase in the number of countries implementing new regulatory requirements to market products in their countries.

In addition to current regulations, there are a number of relatively new acts and directives focused on protecting patients. The two most notable are the United States Food and Drug Administration Safety and Innovation Act and the European Medicines Agency’s Falsified Medicine Directive. One of the key elements of these legislations is to enhance the safety of the drug supply chain.

Regulatory requirements will increase the challenges of working with our supply partners. As the industry moves to place more requirements onto the supplier, we need to ensure both our supply partners and regulatory bodies support the efforts to streamline manufacturing processes. The industry will need to continue to leverage the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

The International Council for Harmonisation’s mission is to make recommendations towards achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical products.
### 8.0 Actions to mitigate the challenges and enable opportunities for improvement

One challenge is to gain agreement on the application of new technologies to support our supply chains. This will require all regulatory agencies to agree to standards that will allow approval across the regulatory network for the new technologies. This will be a major challenge for the industry to overcome to allow our supply partners to meet our expectations. This will require the utilization of agencies such as the International Council for Harmonisation to help make this happen.

Another element that will need to be considered is the fast-track approval of new technologies. Under the current operating model, it may take several years to globally implement new technologies due to the regulatory requirement of the various markets. The fast-track methodology needs to become more of a global standard. This will benefit all parties, suppliers, industry, regulatory bodies and, most importantly, the patients.

The industry will also need to work with global regulatory agencies to standardize quality agreements, certificates of analysis and other relevant documents. One major concern that industry will need to address and work with global regulatory bodies is data integrity. There will need to be alignment across the various regulatory bodies about how they will view data integrity.

Given the level of regulatory compliance in our industry, it will be imperative that we have alignment and support of the global regulatory community to ensure success.

### 9.0 Conclusions and recommendations

#### Conclusions

Supply partnership management is key to the successful implementation of the developments highlighted in the Technology Roadmap.

There is considerable scope for improving the degree of openness and trust that will enable the integration required for EDE systems to truly yield the benefits they offer the biopharmaceutical manufacturing industry. Sharing platform information and standard procedures and processes for the interactions between supply partners and biopharmaceutical manufacturers will result in quality being built in and will drive out non-value-added waste. The understanding and management of supply chain planning are required to support the growth and expansion of the sector. This report recognizes the need for consolidated forecasting and demand planning for sector-critical raw materials and services. For each of these initial areas of interest, there seem to be very few current examples available to be shared.

Supply chain professionals from both sides of the supply partnership management activity need to work in concert to assure regulators and explain the benefits of cross-industry simplification by standardization and the positive impact that it may have on quality and compliance. This effort will lead to the reduction of time to patient for both new products and the delivery of existing ones.

#### Recommendations

The recommendations for further work for the Supply Partnership Management roadmap to consider are:

1. developing the ways of working while collaborating and developing a culture of trust
2. developing EDE as a process with standard applications across the industry
3. engaging with regulators on areas of duplication of requirements and acceptance of developing standard practices
4. assessing the technology developments from Industry 4.0, how they apply to the biopharmaceutical industry and the potential for impact on the inbound supply chain
5. perform a deeper assessment of the capacity to meet the growth needs of the industry in key areas, such as the supply of critical raw materials (e.g. cell culture media components and specialist plastics for single-use systems) and services (e.g. sterilization, lyophilization) with considerations to cross-industry forecasting and demand planning to support the roadmap
6. as the future production of biopharmaceuticals becomes ever more global; supply chains to support the industry continue to be distributed worldwide, and the finished products are also distributed globally, future editions of the Roadmap should consider supply chain mapping and the transportation and logistics of materials.

It is in the interests of all parties involved in supply partnership management for it to be successful. As the sector develops, new relationships will form and evolve, and new supply partners and biomanufacturers will be created through mergers, acquisitions and de-mergers. As the level of supply partner integration increases, the lines of differentiation between supply partners and biomanufacturers will become less distinguishable.
10.0 References


[7] NWWT presentation, Cargill and Smucker’s, October 2016

[8] De Vos F, Sr Manager Supplier Quality, Janssen 2011

[9] Freia Funke


[16] Innovating with the in-crowd: Crowdsourcing is part of an honorable tradition, Strategic Direction, Vol. 29 Iss 8 pp. 9-12 (2013) http://dx.doi.org/10.1108/SD-06-2013-0032


[19] Communicating, Via Cloud, Across the Supply Chain, PYMNTS.com, 12/14/16


### Acronyms/abbreviations

<table>
<thead>
<tr>
<th>Acronym/abbreviation</th>
<th>Definition</th>
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<tr>
<td>API</td>
<td>Active pharmaceutical ingredient</td>
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<td>AQL</td>
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<td>American Society of Mechanical Engineers</td>
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<td>ASTM</td>
<td>American Society for Testing and Materials</td>
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<td>AVA</td>
<td>Adventitious viral agents</td>
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<td>BPOG</td>
<td>BioPhorum Operations Group</td>
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<td>BPOG Supply Partner Phorum</td>
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<td>Rest of world</td>
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<td>United States Pharmacopeia</td>
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12.0 Appendices

Appendix A – Antitrust statement

It is the clear policy of BioPhorum that BioPhorum and its members will comply with all relevant antitrust laws in all relevant jurisdictions:

- All BioPhorum meetings and activities shall be conducted to strictly abide by all applicable antitrust laws. Meetings attended by BioPhorum members are not to be used to discuss prices, promotions, refusals to deal, boycotts, terms and conditions of sale, market assignments, confidential business plans or other subjects that could restrain competition.

- Antitrust violations may be alleged on the basis of the mere appearance of unlawful activity. For example, discussion of a sensitive topic, such as price, followed by parallel action by those involved or present at the discussion, may be sufficient to infer price-fixing activity and thus lead to investigations by the relevant authorities.

- Criminal prosecution by federal or state authorities is a very real possibility for violations of the antitrust laws. Imprisonment, fines or treble damages may ensue. BioPhorum, its members and guests must conduct themselves in a manner that avoids even the perception or slightest suspicion that antitrust laws are being violated. Whenever uncertainty exists as to the legality of conduct, obtain legal advice. If, during any meeting, you are uncomfortable with or questions arise regarding the direction of a discussion, stop the discussion, excuse yourself and then promptly consult with counsel.

- The antitrust laws do not prohibit all meetings and discussions between competitors, especially when the purpose is to strengthen competition and improve the working and efficiency of the marketplace. It is in this spirit that the BioPhorum conducts its meetings and conferences.
Roadmap intended use statement
This roadmap report has been created and is intended to be used, in good faith as an industry assessment and guideline only, without regard to any particular commercial applications, individual products, equipment, and/or materials.

Our hope is that it presents areas of opportunity for potential solutions facing the industry and encourages innovation and research and development for the biopharmaceutical industry community to continue to evolve successfully to serve our future patient populations.

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