Hello,

The focus for this March newsletter is tangible outputs and contribution to business benefits; five excellent examples from the Phorum teams. I hope you enjoy reading about them. April is a busy month for face-to-face meetings and these are listed for your information. Questions and feedback are always welcome.

Regards,

Simon Chalk

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**BPOG work with ANVISA to reduce approval times by up to a year**

BPOG is working together with Brazil's ANVISA to help increase the rate at which approvals are made up a year. The current approval timeline in Brazil is between 18 months and two years, it is the intention of the Post-Approval Strategies (PAS) workstream to reduce this and support ANVISA to harmonize their approvals with the International Congress for Harmonization (ICH) of which ANVISA are now members.

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**New BPIT guidance to align cloud services to regulatory requirements**

Cloud services are being increasingly used to provide a cost effective and flexible platform for software. As GxP systems increasingly move onto the cloud, agreement is vital for both provider and customer responsibilities to maintain compliance. For example, how does the provider ensure the security of the underlying infrastructure? Does the provider utilize commercially available software products that are developed and tested to IT industry standards? And does the customer perform periodic reviews of their provider configurations and the systems they deploy? With a lack of clarity on questions such as these we open ourselves up to both risk and a lack of consistency across the industry.

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**Two Multi-Product Facility papers published in PDA to improve changeover processes**

The Multi-Product Facility workstream have two closely related papers published in the PDA which together will allow companies to reduce the time they take in changing over from one product to another. Both papers use a quality risk management approach to systematically identify the best way to manage the changeover processes and can offer substantial value when fully realised.
Up to 50 per cent cost reduction from CNC environment use

Over the last three years BPOG has entered into a collaboration with the Biomanufacturing Training and Education Center (BTEC) at NC State University, to undertake bioburden reduction studies on hybrid (stainless steel and disposable) functionally closed bioprocessing systems.

Breakthrough Therapies Team Encouraged to Publish

Following our preview in the December newsletter [insert link], the Development Group’s CMC Considerations for Expedited Development Point Share recently presented a poster at the CASSS WCBP meeting in Washington, USA over 30 January to 1 February 2018. The poster summarizes this industry group’s collective thoughts on opportunities and challenges of CMC development under accelerated registration pathways - with a focus on breakthrough therapy designation.

New Members

The BPOG communities are more popular than ever as more and more companies are joining our collaborations. This month we welcome five additional members to the Phorums with some joining their first BPOG Phorum and others, such as Sanofi, becoming involved in all the Phorums now that they have joined Fill Finish.

Another biotech bay company, BioMarin, based Marin County, CA have joined Drug Substance this month. BioMarin focus on developing first-in-class and best-in-class therapeutics that provide meaningful advances to patients who live with serious and life-threatening rare genetic diseases. Not only do they bring in new sites and minds from the north of bio-tech bat into our group but also old friends from an ex-Pfizer site in Ireland.

BPIT are experiencing a massive expansion and now have 21 members of the Phorum with the new additions of Takeda and Bayer to the collaboration. BPIT also welcome their first supply chain member, GE, for the information technology community.

Finally, Chugai are now members of Technology Roadmapping and we know they will enjoy the upcoming steering committee meeting in Philadelphia, PA this coming May.

New Facilitators and Event Manager

You may have noticed we’ve had a significant increase in meetings this year due to the growing demand of the collaboration.

We have increased our support team with the welcome addition of Caron Diggory who will be working on our Events Management team. Caron joins us from Shakespeare’s home town of Stratford-upon-Avon. After a successful career in the publishing world where she was responsible for the sales and marketing of English-language titles across Asia and Africa, Caron is well versed in planning and attending international meetings and conferences. In recent years, she has worked as a private tutor teaching German and French. After years of travelling herself, she is now happy to have her feet firmly on the ground and relishes the opportunity to organize successful international events for everyone else.

In other news we are preparing for the possible launch of a new Phorum in the coming months focused on Cell and Gene Therapy Phorum, and have recruited Helen Hay as a facilitator. She
It comes to us after a 17 year career as a PMP certified project manager at GE Healthcare, although
she is keen to point out that it is good people and not just good processes that deliver successful
projects. She is keen to apply her PhD in Genetics and Molecular Biology within BPOG and is
looking forward to meeting some of you in the near future.

Upcoming Face-to-Face Meetings:

Extractables and Leachables 03 (Drug Substance) - 10-12 April 2018, Cambridge,
Massachusetts, USA - to look at the community of practice and supplier collaboration.

Pre-Use Post Sterilization Integrity Test 01 (Fill Finish) - 10-11 April 2018, Washington
DC, USA - launch the PDA/BPOG PUPSIT program. Plan out the approach to the masking study
and PUPSIT best practice work.

Industry Capacity Constraints Analysis 02 (Supply Partner Phorum) - 12-13 April 2018,
Research Triangle Park, Raleigh/Durham, North Carolina, USA - to provide an assessment
of global manufacturing capacity of aggregated raw material consumption, analyze the data to
assess what, if any, constraints may apply in anticipated industry capacity growth.

Forecasting and Demand 02 (Supply Partner Phorum) - 17-18 April 2018, Charleston,
North Carolina, USA - to create a pathway to implementation, change, and value realization
within supply chain forecasting and promote our Best Practice Guide.

Compliance 03 (Information Technology) - 18-19 April 2018, Baltimore, Maryland, USA -
develop the value propositions, plans, approaches and deliverables for the Agile playbook and
Compliant MultiSource Analytics. Additionally, to shape Data Integrity Framework’s for Vendors
and CMO’s for 2018 kick off decision.

Small Flexible Fillers 01 (Fill Finish) - 18 April 2018, New York, USA - launch of small
flexible filler URS with suppliers alongside INTERFEX.

Microbial Control 02 (Drug Substance) - 24-26 April 2018, Leiden, Netherlands - detailed
planning and group work to progress the Microbial Control five year plan.

Supply Base Reliability (Drug Substance) - 24-26 April 2018, Oakland, California, USA -
this meeting will formally see the launch and detailed planning of the workstream.

BioPhorum 15 - 15-17 May 2018 - Texas, USA

Drug Substance Core Team Meeting 31 (Drug Substance) - 24-22 May 2018, Cork,
Ireland - focus on co-implementation of single use user requirements, change notification, raw
materials variability, and consideration of strategic new topics through review of the Technology
Roadmap and other external stimulus.

Technology Roadmapping Steering Committee Meeting 07 (Technology Roadmapping)
- 23-24 May 2018, Philadelphia, USA - steering committee meeting to review overall program.
Plan strategy for publishing second edition roadmap plus a review of current projects and
decisions.

GDPR

If you are based in Europe you may be aware that there is a new data protection law in
place from 26 May 2018. Over the next three months we will be asking you to opt-in to our
mailing list so that we remain fully compliant with the changes in law. If you want to keep
receiving our newsletter, please click on the link below: