Introduction

Problem statement
• communicating requirements of single-use systems frequently exposes gaps in expectations between end users and suppliers

Proposed solution
• equip the industry with common tools to enable clear and consistent communication of user requirements and supplier capabilities in accordance with ASTM E3051

The focus of this presentation is guidance on how to use the URS toolkit
High level process overview – per project

End User

- **COMMUNICATE USER REQUIREMENTS**
  - Complete BPOG/BPSA SUUR template and submit to supplier(s)

Supplier

- Communication to align user requirements and supplier capabilities can be iterative

  - REVIEW SUUR and provide individual responses on whether each requirement can be met

DEVELOP DESIGN

- Generate assembly drawing based on SUUR

  - Development of design details can be iterative

DEVELOP DESIGN

- Review drawing and confirm design expectations are met

  - Proceed to design qualification
High level process overview – per project (continued)

**End User**
- **QUALIFY DESIGN**: Submit technical diligence template to initiate communication with supplier(s) to verify what qualification activities have been performed by supplier.
  - As required, end user and/or supplier to perform additional qualification to verify that user requirements are met.
- **FINALIZE AND REVIEW DESIGN**: As required, make final design updates based on qualification activities and perform design review.
  - Submit supply chain template for visibility on final design components.

**Supplier**
- **QUALIFY DESIGN**: Provide completed technical diligence template to end user.
- **FINALIZE AND REVIEW DESIGN**: Provide completed supply chain template to end user.
- **IMPLEMENT**: Implement SUS following appropriate business processes.
How to use User Requirements Template – End User

- The first step is to summarize the application, detailing how the assembly will be used through its lifecycle – do not assume that the supplier is familiar with the intended use.

Without sufficient knowledge of the application, suppliers cannot ensure that the design, materials of construction, and level of qualification are appropriate for the end user.
the bulk of the User Requirements template is populating the four sections of the template: Functional, Qualification, Quality, and Supply Chain requirements

- given the breadth of the requirements included, a cross-functional team must be engaged to fill out the various sections - as part of implementing this URS toolkit, buy-in from all stakeholders is needed up front
- guidance for populating each requirement is embedded in the template – there is flexibility to provide additional requirements

<table>
<thead>
<tr>
<th>ID</th>
<th>REQUIREMENT DESCRIPTION</th>
<th>SUPPLIER RESPONSE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>FUNCTIONAL REQUIREMENTS</strong></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Operating temperature and temperature change:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Operating</td>
<td>Min (units)</td>
</tr>
<tr>
<td></td>
<td>□ Freezing/Thawing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Heat Sterilization</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Other: _______________</td>
<td></td>
</tr>
</tbody>
</table>

End user SME to populate

- note that the template contains a list of potential requirements that is likely to exceed what is required for the application – the end user is expected to indicate which requirements are not required/applicable on the template
- standard requirements may be pre-populated as part of templates

The value of the template is to simplify compilation of requirements by the end user and present them in a consistent manner to suppliers
How to use User Requirements Template – Supplier

• End users expect a response from the supplier on whether each requirement is met, and if not, what the exception is
  • it is not expected for an explanation of how the requirement is met to be included in the User Requirement Template response – that detail will be communicated in the Technical Diligence Template

• given the breadth of the requirements included, a cross-functional team must be engaged to respond to the various sections - as part of implementing this SUUR toolkit, buy-in from all stakeholders is needed up front
• standard responses may be pre-populated as part of templates

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<tr>
<td></td>
<td>□ Other:_________________</td>
<td></td>
</tr>
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Supplier SME to populate

The supplier response provides the end user with confirmation whether the requirement is met
How to use Technical Diligence Template (TDT) – per project

• the objective is to provide at least those supplier responses in the TDT that are relevant to a project specific User Requirements template
• the project specific section of TDT should be submitted by the end user along with the completed User Requirements template as part of the request for proposal
• standardized requests for information enable suppliers to prepare standardized responses across customer base
  • initially, suppliers will be building up the responses and may not be able to provide comprehensive responses immediately

<table>
<thead>
<tr>
<th>Operating Pressure &amp; Temperature</th>
<th>Supplier’s Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Requested Information</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Test Method:</strong> Test Method or Standard used to determine pressure and temperature limits. State acceptance criteria and/or definition of failure (e.g., due to excessive pressure).</td>
<td>Supplier SME to populate</td>
</tr>
<tr>
<td><strong>Test Article:</strong> Design and description of the test article assembly used to establish pressure and temperature specifications. Justification for using this assembly (if the assembly is used as a product family representative). Pretreatment (e.g., autoclaving or gamma irradiation) of the test article prior to testing. Justification for pretreatment strategy.</td>
<td>Supplier SME to populate</td>
</tr>
</tbody>
</table>

End users are accountable for ensuring supplier responses are appropriate
How to use Technical Diligence Template (TDT) – qualifications

- the objective is to provide a comprehensive supplier response in the TDT to enable a technical diligence program
- the qualifications section of TDT are not project specific and should be submitted by the end user as appropriate for their technical diligence program
  - it is recommended the end user submit the template prior to a physical visit – depending on the purpose and scope of the diligence activity, and the quality of the supplier responses, a paper exercise may be sufficient
- standardized requests for information enable suppliers to prepare standardized responses across customer base
  - initially, suppliers will be building up the responses and may not be able to provide comprehensive responses immediately

<table>
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<tr>
<th>Endotoxin</th>
<th>Requested Information</th>
<th>Supplier’s Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conformance to compendial standards</strong> (i.e.: USP &lt;85&gt;, EP 2.6.14)</td>
<td></td>
<td>Supplier SME to populate</td>
</tr>
<tr>
<td><strong>Test article:</strong></td>
<td>Description of the test article configuration and composition</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Description of how the test article is representative of actual sellable SUS product</td>
<td></td>
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<tr>
<td><strong>Test article preparation:</strong></td>
<td>Differences from manufacturing of sellable SUS product</td>
<td></td>
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<tr>
<td></td>
<td>Post-manufacturing manipulations (e.g., cutting, disassembly)</td>
<td></td>
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</tbody>
</table>
How to use the Supply Chain Template

- the Supply Chain Template should be completed by the supplier once the design is finalized
- this timing is to avoid unnecessary churn with supply chain information during design development/iterations
- supply chain transparency is critical for enabling end users to perform informed risk assessments and verify that requirements are met

NOTE: The table below allows the end-user to request certain supply chain-related details for the components listed in the Bill of Materials (BOM) of the drawing, and it allows the supplier to respond to this request.

Component information for the supplier part number is:

- [ ] Provided below
- [ ] To be provided in the near future: ____________
- [ ] Not to be provided

<table>
<thead>
<tr>
<th>BOM Item No.</th>
<th>Component Part No.</th>
<th>Material(s) of Construction</th>
<th>Manufacturer</th>
<th>Component Manufacturing Site(s)</th>
<th>Component Manufacturer Part No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Items Requested by End-User Are Indicated by Check Box Below

- [ ]
- [ ]
- [ ]
- [ ]
- [ ]
- [ ]

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Next steps for consideration

• For additional information, reference suite of documents:
  • Guideline for use and implementation of SUUR Toolkit
  • FAQ
  • business benefits wheel
  • elevator pitches
• For any additional questions, contact userrequirements@biophorum.com
• www.biophorum.com/SUUR
• http://bpsalliance.org/
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