



Guideline for Use of Single-Use User Requirements (SUUR) Toolkit

Joint BioPhorum / BPSA Team

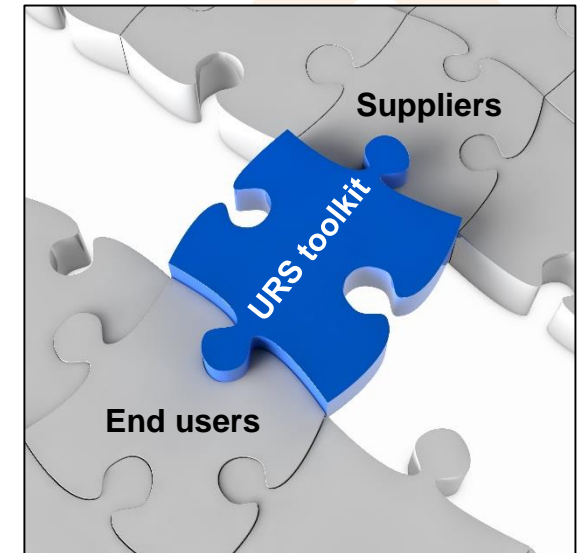
Introduction

Problem statement

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

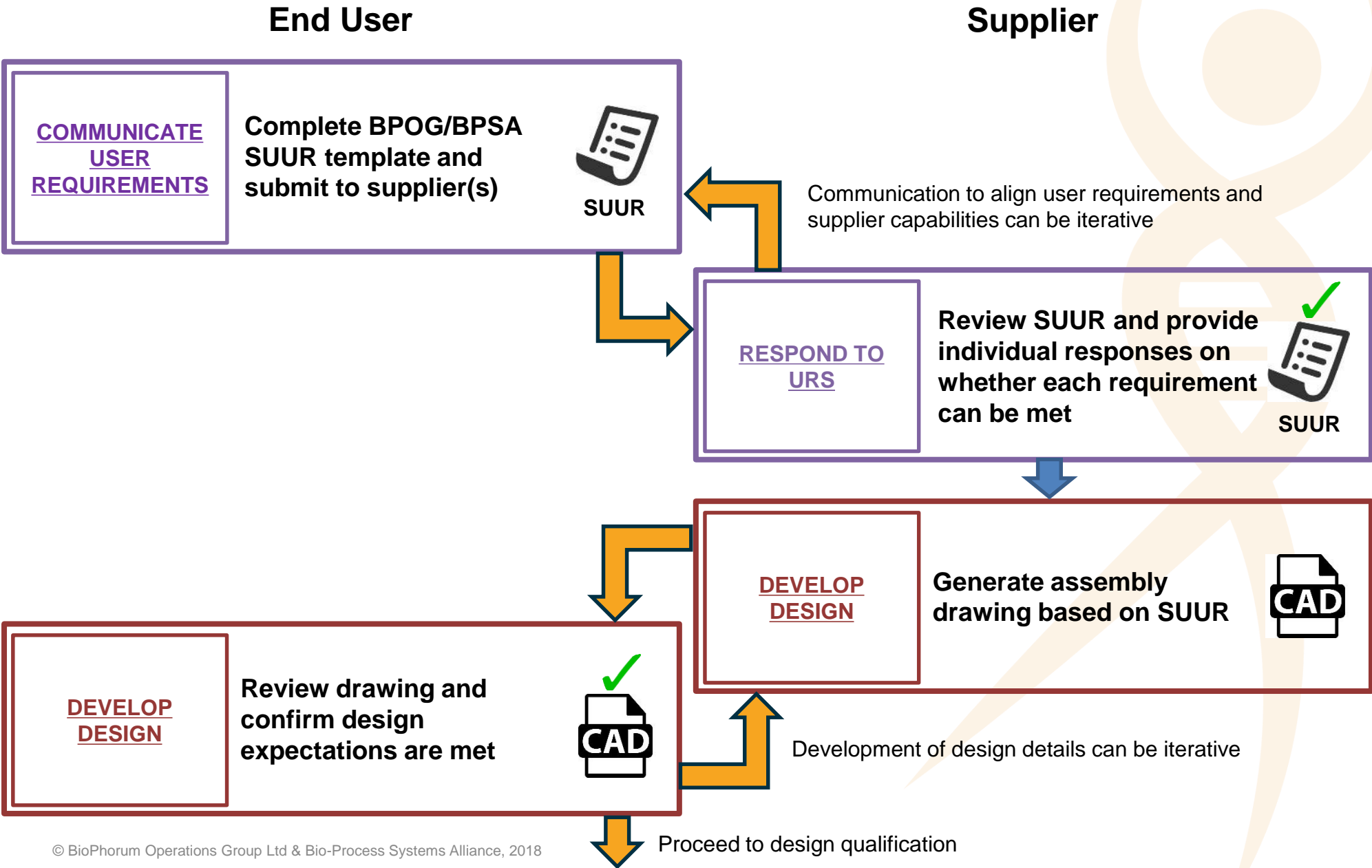
Proposed solution

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

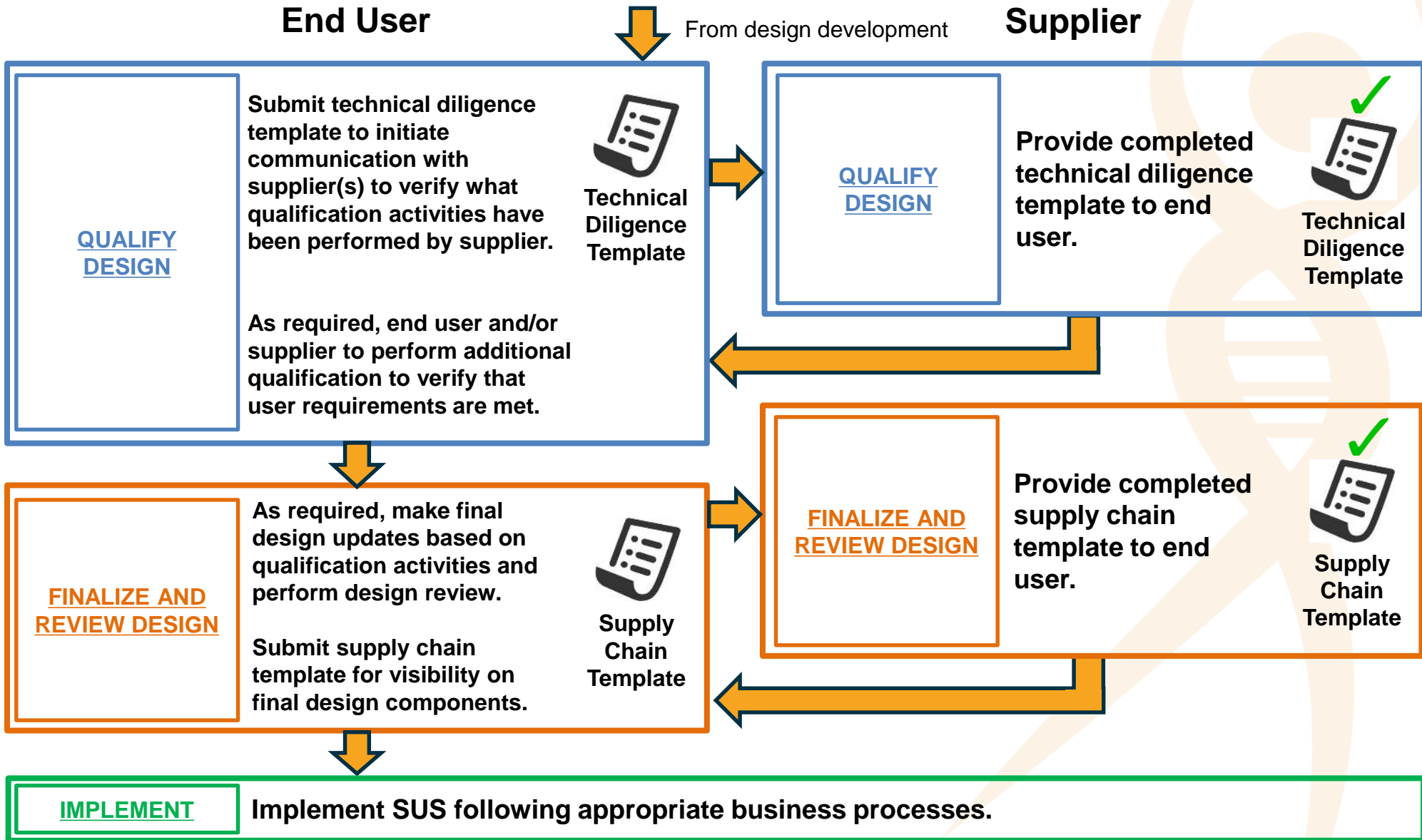


The focus of this presentation is guidance on how to use the URS toolkit

High level process overview – per project

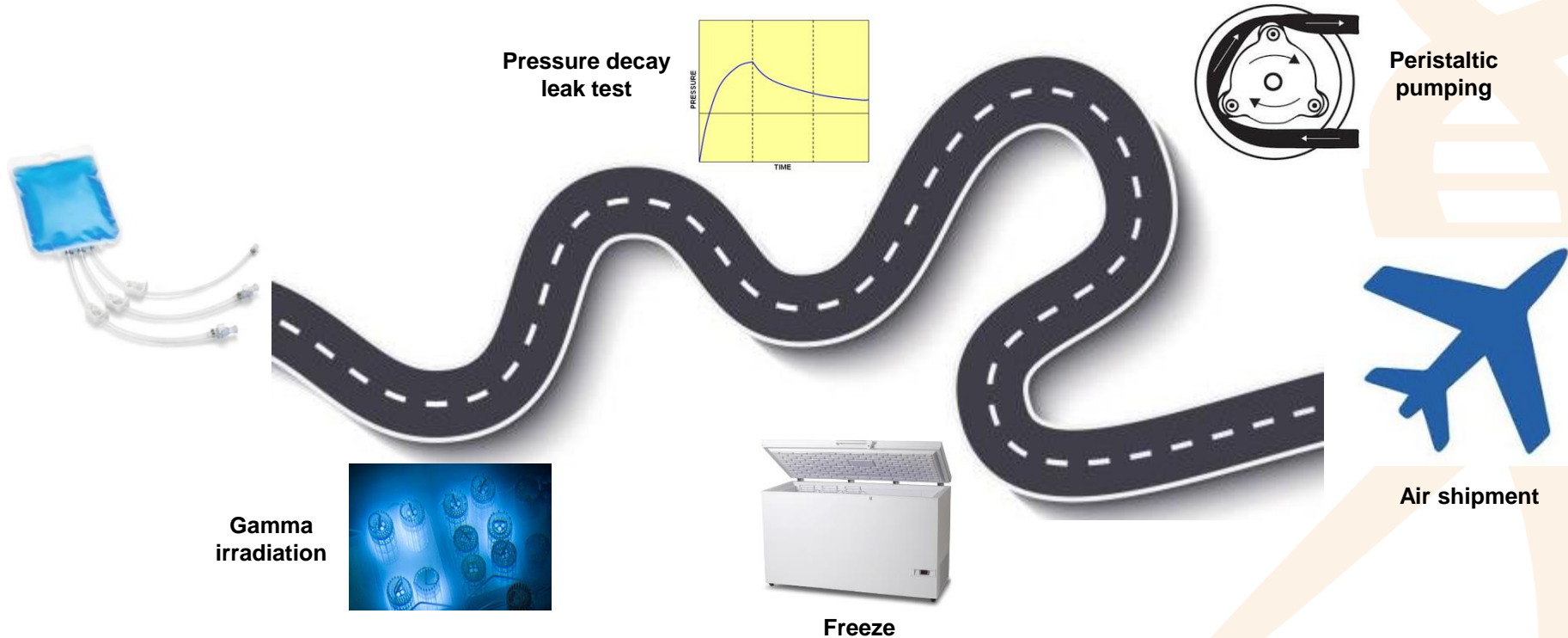


High level process overview – per project (continued)



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

How to use User Requirements Template – End User (continued)

- 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

ID	REQUIREMENT DESCRIPTION	SUPPLIER RESPONSE
FUNCTIONAL REQUIREMENTS		
1.	Operating temperature and temperature change:	
	<input type="checkbox"/> Operating	Min (<i>units</i>) Max (<i>units</i>)
	<input type="checkbox"/> Freezing/Thawing	
	<input type="checkbox"/> Heat Sterilization	
	<input type="checkbox"/> Other: _____	

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

ID	REQUIREMENT DESCRIPTION	SUPPLIER RESPONSE	
FUNCTIONAL REQUIREMENTS			
1.	Operating temperature and temperature change:		
		Min (<i>units</i>)	Max (<i>units</i>)
	<input type="checkbox"/> Operating		
	<input type="checkbox"/> Freezing/Thawing		
	<input type="checkbox"/> Heat Sterilization		
<input type="checkbox"/> Other: _____			

Supplier SME to populate

- 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

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

Operating Pressure & Temperature	
Requested Information	Supplier's Response
Test Method: 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).	Supplier SME to populate
Test Article: 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.	

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

Endotoxin	
Requested Information	Supplier's Response
Conformance to compendial standards (i.e.: USP <85>, EP 2.6.14)	Supplier SME to populate
Test article: Description of the test article configuration and composition Description of how the test article is representative of actual sellable SUS product	
Test article preparation: Differences from manufacturing of sellable SUS product Post-manufacturing manipulations (e.g., cutting, disassembly)	

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**

BOM Item No.	Component Part No.	Material(s) of Construction	Manufacturer	Component Manufacturing Site(s)	Component Manufacturer Part No.
Items Requested by End-User Are Indicated by Check Box Below					
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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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