BPOG and BPSA User Requirements for Single Use Systems
Agenda

- Background: SUS Requirements Joint Team
- BPOG Member Survey
- Next Steps
How did we get to this point?

GMP Expectations Gap
- GMP Expectations Webinar (Q3-Q4 2014)
- GMP – Survey of End users (March 2015)

Form the team
- BPOG Disposables ‘Face to Face’ Meeting – Decision to form a team to work on ‘Single Use - User Requirements’ (April 2015)
- Decision to form a joint team with support from BPSA. (Q2 2015)

Mobilize & Communicate
- BPSA Summit (July 2015)
- BPI Conference (October 2015)
### Current Team Members

(15 End Users / 12 Suppliers)

<table>
<thead>
<tr>
<th>End Users</th>
<th>Suppliers</th>
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<tbody>
<tr>
<td>Abbvie</td>
<td>Colder</td>
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<tr>
<td>Amgen</td>
<td>Dow Corning</td>
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<td>Astra Zeneca</td>
<td>Entegris</td>
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<td>Baxalta</td>
<td>GE Healthcare</td>
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<td>Biogen</td>
<td>Millipore-Sigma</td>
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<td>BMS</td>
<td>Meissner</td>
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<td>GSK</td>
<td>NewAge Advantapure</td>
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<td>GSK Biologicals</td>
<td>Nordson Medical</td>
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<td>Lonza</td>
<td>Sartorius Stedim</td>
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<td>Merck</td>
<td>Saint-Gobain</td>
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<td>Novavax</td>
<td>Thermoscientific</td>
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<tr>
<td>Regeneron</td>
<td>Value Plastics</td>
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<td>Roche</td>
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<td>Sanofi Pasteur</td>
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Excerpt from GMP Expectations Webinar

‘Single Use Systems provide significant operational benefits’

‘However too often implementations of Single Use Systems in GMP Operations expose a gap in expectations between Supplier and End User on GMP’

- For Single Use Systems to be the **system of choice** for GMP operation, the gap needs to close by creating a standard set of requirements.
- Government agencies hold End Users accountable for any deficiencies in the quality of materials and data acquired from suppliers.
- End Users require systems around Single Use Systems to provide the same level of assurance as conventional stainless steel provides; this is driven by defined user requirements.
Excerpt from GMP Expectations Webinar

‘Collaboration of Suppliers and End Users is vital to the establishment of standard user requirements that are harmonized and at the same time defendable to regulatory inspection’

Supplier 

A strong foundation for the creation of Single Use System standards and ways of working.

End User 

A consistent, defendable position for regulatory inspection.

More rapid integration of Single Use Systems into Commercial and Late Phase programs.

Accurate knowledge of Customer’s needs, reducing waste for all concerned.
The ‘New Reality’ for Single Use Systems

As Single Use System assemblies replace traditional equipment, the Supplier starts to own a larger portion of the supply chain and the End User’s direct control diminishes.

But the End User remains accountable!

Disciplined development of URS

Uncharted space - Ad-hoc development of needs/requirements

Disciplined development of URS

Needs to be

Supply Chain Partnership
Requirements of Single Use Systems in a Commercial Operation

- Meet Agency Requirements
- Control of Supply Chain
- Quality and Compliance

*Shared Responsibility (End users and Suppliers)*
Agenda

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GMP Expectations Survey of End Users

The survey was designed to gather feedback focused on three main stages of evaluation of a Supplier by an End User:

1. Pre-evaluation of Single Use System
   - What is important and where do you focus before you implement SUS?
   - Component production, understanding the film system, engagement qualification, etc...

2. Quality System Requirements (verified during audits)
   - What is important and what do you ask about during audits?
   - Environment, documentation, equipment, sterilization validation

3. Product Specification Requirements
   - What information do you ask for when your product arrives for use?
   - QC release testing, visual inspection criteria...

15 End User companies participated
### GMP Expectations Survey of End Users

Participant Responses were reviewed using a heat map approach.

<table>
<thead>
<tr>
<th>Pre-evaluation of SUS system</th>
<th>We get this every time</th>
<th>We sometimes get this</th>
<th>We never get this</th>
<th>We never ask this</th>
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<tbody>
<tr>
<td>High Importance</td>
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<table>
<thead>
<tr>
<th>Quality system requirements (audits)</th>
<th>We always review this</th>
<th>We sometimes review this</th>
<th>We never review this</th>
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</thead>
<tbody>
<tr>
<td>High Importance</td>
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<th>Product Specification Requirements</th>
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Survey Results
(Pareto Chart - Dissatisfaction levels)

Class VI and Shelf-life Studies reached high satisfaction levels

<table>
<thead>
<tr>
<th>Aspects addressed</th>
<th>5</th>
<th>10</th>
<th>17</th>
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<tbody>
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<td>Improvement (%)</td>
<td>23</td>
<td>54</td>
<td>82</td>
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GMP Expectations Survey of End Users

Overall survey results showed the following:

– The areas of focus chosen were of high importance to most companies.

– Companies have varying levels of success getting this information. Why?
  • Is the information not known?
  • Can this information not be shared?
  • Do different company approaches generate different results?
  • Does company size have an effect (both supplier and end user)?

– Those which were ranked of high importance are opportunities to collaborate and understand best practice.

– There was a 50/50 split of end user companies who have suppliers that cannot be used because they cannot meet GMP expectations.
GROUPING OF SURVEY RESULTS PER JOINT DISCUSSION

ALIGNMENT OPPORTUNITIES

MOC of Film & Components
- MOC
- Supply Chain transparency
- Understanding film props and other components (+ tubing, connectors, etc....)
- Film Layer identification

Mfg. systems / practices / education
- KPI during mfg.
- Sup. Documentation Practices
- Sup. Equip. Mgmt. Program
- Operator Training Program
- Reluctance to work with some suppliers

Visual release criteria
- Particulate / visible
- Supplier Inspection of SU
- No delamination or defective seals
- No esthetical defects
- Bioburden sampling
- LAL product per lot
- Monster assembly (LAL and validation, bioburden)
- ISO 11137 Validation

C of A Release

Incorporates the performance of application / assembly

Includes the performance of application / assembly

Integrity / Performance

Mfg environment

DISSATISFACTION
Areas of Focus Established from the Survey Results

Pre-Evaluation
- MOC
- Integrity / Performance

Supplier Qualification/Capabilities
- Manufacturing Systems / Practices / Education
- Manufacturing Environment

Product Specification
- Visual Release Criteria
- C of A Release
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Joint Team - Plan

Form collaboration between End Users and Suppliers to develop a joint path forward for the creation of Standard User Requirements

Review feedback from end user survey to help narrow down to the focus areas

Establish scope and strategy

Publish guidance based on joint work – through articles, development of standards for SUS, etc....

Obtain feedback and revise guidance as appropriate.
Outputs

User Requirements

- Pre-evaluation
- Supplier Audits
- Product Specification

White Paper Guidance & User Requirement Documents
Supplemental Audit Guide
White Paper Guidance
Participate!!

Let us know!

- Key concerns?
- Ideas?
- Best practices?

Tell people in your company about this effort.

Please share your feedback or express your interest via e-mail

Email your feedback and comments to: userrequirements@biophorum.com