BioPhorum Operations Group

FlyPharma Conference
Brussels, June 7-8 2016
Today’s Presentation

- BPOG… Who they are & what they do?
- Recognising the common challenges and opportunities across traditional BPOG areas of interest and Pharma Logistics
- Status of the BPOG work in this area
About BioPhorum

- **BioPhorum Operations Group (BPOG)** is a powerful cross-industry collaboration
- Members include Biopharmaceutical Developers, Manufacturers & Suppliers
- We design and manage programs of collaboration for 6 distinct communities;
  - Drug Substance Manufacturing
  - Drug Development
  - Sterile Drug Product Operations (Fill Finish)
  - Information Technology
  - Inbound Supply Chain
  - Technology Roadmap
- The BioPhorum collaboration communities together represent 90% of the global biopharmaceutical manufacturing capacity.
- BPOG provides professional facilitation capability and processes to support cross-company collaboration teams.
BPOG’s mission is to accelerate the advancement of biologics manufacturing in terms of product and process quality

- 1800 active participants
- 40 current working groups
- 25 F2F mtgs/yr
- 30 papers published since 2012
- 60 Conference presentations since 2012
- 25 Facilitators
- 90% of Biopharmaceutical manufacturing capacity represented

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6 Phorums covering all aspects of operations and accelerating biopharma industry’s journey to maturity

- **Drug Substance, Fill Finish, Development Group and IT Phorums**
  - Accelerate the way the industry delivers near term results making best practice development and implementation faster, cheaper and smarter

- **Supply Partner Phorum**
  - Strategic focus on the wider supply chain needs of the industry; defining, developing & implementing solutions
  - Focus on business processes/systems & culture

- **Technology Roadmapping**
  - Revolutionise the way the industry develops longer term transformational manufacturing and technology capabilities
  - Focus on longer term strategy & 10+yr time horizon, defining needs, difficult challenges and potential solutions

- **Regulatory Interactions Group**
  - Engage and align with Health Agencies in the design and adoption of advances in manufacturing

**BPOG manages the linkages to ensure**
- Decisions are made at the right time, at the right place by the right people
- Linkages are made visible to avoid redundancy
- Synergies are leveraged through effective coordination
It’s all about ACCELERATING the rate of maturity of the industry through collaboration

Can only be achieved through effective collaboration with all the key stakeholders:

- Regulatory Agencies
- Supply base
- Other Industry bodies
Management, Notification, and Documentation of Single-Use Systems Change Orders: Challenges and Opportunities

by Tony White and Kevin Ott

Single-use systems (SUS) create invisible plastic pipes and pumps, which are now a critical part of the manufacturing process. Changes may originate at the immediate supplier or filtered back to the supply chain as a result of product improvement, process improvements, part discontinuations, or even business decisions such as manufacturing site relocation. Whether these changes are major or minor, ensuring these impacts are communicated to the appropriate parties is crucial. Successfully managing the product quality often is a difficult undertaking in view of regulatory requirements.

The issue of change notifications for SUS is new. Single-use plastic manufacturing equipment such as filters and bags has been used for decades. However, until now, an industry-wide effort to standardize the process has not been undertaken, and best practices have not been established. Given the rapid uptake of SUS, there is a clear need for efficient, effective, standardized change notifications that apply to the biopharmaceutical industry. This article discusses the key elements needed for successful change notifications and includes a case study involving a multi-functional team of suppliers and end users from BioPhorum Operations Group (BPOG) and BioProcess International (BPI).

BPOG MEETING WITH FDA POINTS TO PROMISING FUTURE DIALOGUE:

BPOG's 25 representatives (drawn from a wide cross-section of member companies and strategically worked normal) had an introductory meeting May 17th with 17 of the FDA's technical experts and directors from CDER/CBER.
BioPhorum Information Technology (BPIT)

- This is a new Phorum providing an opportunity for the IT people to collaborate on experience and positions.
- Inaugural meeting in 2015 with primary objective to explore common themes and topics.
- The tech industry is entering into a highly collaborative mode as it develops the industrial internet (Industry 4.0). Need to understand what new technologies are relevant. Open standards becoming more important across the ecosystem.
- In BPIT, three key areas were selected as common strategic themes:
  - Digital Plant
  - Predictive Analysis,
  - Talent Management.
This will be achieved by...

• Active participation in a proven and clearly defined industry collaboration model

• Encouraging collective investment in mutual understanding, new ideas and approaches

• Striving to attain world class practices and performance

Transforming the inbound supply chain for the benefit of end users, suppliers and patients alike, resulting in a:

• Step reduction in risk, non value adding waste and lead times

• Step increase in reliability and quality compliance
Regulatory Interactions Group

**Problem**
- Industry continues to develop advanced, best practice manufacturing processes, systems, technologies and facilities; however, an unwelcome sense of uncertainty predominates, driven by varying levels of confidence that agencies will accept these improvements once implemented.

**Impact**
- Best practice is diluted as a mitigation against potential rejection
- Solutions are over engineered and are cumbersome and costly
- Innovation and improvement is slowed; status quo prevails
- Ultimately speed to market, supply assurance and cost are negatively impacted

**Benefits**
- Increased mutual understanding of key positions and challenges in implementing new biomanufacturing practices
- Pooled company intelligence of how different agencies are approaching guidances and challenges
- Opportunity to educate agencies on best practice approaches to increase positive submission and inspection outcomes

**End Goal**
- Ongoing platform of informal dialogue with agencies in order to offer industry views and listen to wider agency perspectives, prior to implementation
- Share industry positions on priority topics with agents and solicit feedback from informal touch points with regulators across the member companies
An industry technology roadmap is – a dynamic and evolving collaborative technology management process for

- determining precompetitive critical needs and drivers,
- identifying technology and/or manufacturing targets, and
- assessing/modeling potential solutions to
  - focus an industry community,
  - provide direction, and
  - resolve those critical needs for a specific timeframe by consensus.

Goal is to agree an industry technology strategy
BPOG25 Meeting
DS Transport & Storage

BRUSSELS, MARCH 2016
Patients have a right to expect their medicines to be delivered to them at the right quality and trust the supply chain to deliver them uncompromised.

As an industry we are at risk of losing this trust if we can’t evolve to address the following pressures.

The context..
Medicines for all is contributing towards a **60% growth** in pharma use of cold chains

Examples of **redundancy**, repeated and non-value adding work in the E2E supply chain

**Variability** in design and operation of processes used

Pharma represents **3% of airfreight industry** and has relatively low level of influence

**Multiple approaches** in the validation and qualification of equipment, lanes and service providers

Service providers often not meeting **biopharma industry’s needs**

**Inconsistent** interpretation of regulatory requirements and filing approaches

Globally consistent processes and risk appropriate packaging will be key
These consequence of not doing something about this...

- Risk to patients
- Expensive recalls
- Loss of confidence in the company/Brand
- Regulatory action
- Loss of revenue
- Suspension of manufacturing/distribution authorisation
- Compulsory variation of authorisation
- Revocation of authorisation
- Sanctions against the QP or RP
- Over-engineered and costly solutions
This is what we need to do...

- Create collaborative, value adding partnerships across the whole supply chain
- Leverage networks to achieve the desired end-state
- Engage and educate regulators
- Raise the competence of staff across whole supply chain
- Learn from other industries
- Define and adopt required standards globally
Transport & Warehousing... BPOG’s interest...

• Transport & Warehousing was identified as an area of interest for BPOG members in 2015
• 17 manufacturers of biopharmaceuticals met in Brussels in March 2016 and agreed to work collaboratively on issues related to Storage and Transport
• Issues faced include:
  • Wide degree of process variability
  • Unclear user requirements
  • Inconsistent filing methodologies
  • Issue of redundancy in E2E supply chain
  • Multiple approaches to validation / qualification
• The scope of work will include drug substance (DS) and drug product (due to the similarity of the issues faced)
• Proposed areas of activity include:
  • Regulatory guidance for shipping filing information;
  • Standard frozen DS storage temperature ranges;
  • Standard for operational qualification and performance qualification;
  • Database of qualified solutions.
• Scoping is underway and expect mobilisation of a workstream in Q3 2016
Today’s Presentation

• I’ve given you some background on who BPOG are and the areas where members are delivering value through effective collaboration.

• I’ve highlighted where the challenges and opportunities recognised within the Pharma Logistics sector are common across other areas of Biopharma:
  • Opportunities to increase understanding & awareness of needs
  • Opportunities to drive standardisation and consistency

• Pharma Logistics is a new areas of interest for the BPOG workgroup and they are at the early stages of scoping out the areas where industry collaboration makes sense.
Thank You