



2014 PDA ANNUAL MEETING

*Biopharmaceutical and Sterile Manufacturing –
Embracing Innovation to Meet Global Challenges*

April 7-9, 2014

**JW MARRIOTT SAN ANTONIO HILL COUNTRY
SAN ANTONIO, TEXAS**



EXHIBITION: APRIL 7-8
POST-CONFERENCE WORKSHOP: APRIL 9-10
COURSES: APRIL 10-11

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Monday, April 7, 2014

IG3: Outsourced Operations

Task Force Co-Chairs

Sue Schniepp

Karen Ginsbury

Session Leader: Karen Ginsbury

Agenda

- Introductions
- Quality Agreements
- Culture, Cooperation, Communication
- Risk management / assessments
- Regulatory inspections
- Batch release
- Quality Metrics
- Other...

Topics of Raised by Participants

- Communication strategy with CMOs which are getting bigger (elephant vs ants) - resources needed for managing outsourced operations
- (tech transfer and other milestones)
- Supporting external assets
- Challenges and opportunities – alliance and sharing
- How to manage CMOs in the US

Topics of Raised by Participants

- Outsourcing development – other people slotting into our model – communications
(we know what we are doing – time allocation)
- Initiation – do it right first time (too much time upfront)
- Regulatory perspective of inspection and oversight of CMOs
- Change control / case studies / whitepapers
- Strategy for documenting risk – ***develop a risk assessment tool***
- Capabilities – understand them and listen

Topics of Raised by Participants

- Testing / transfer of assays – getting it right
- Expectations – big pharma vs little CMO
- Proactive – hear the voice of the customer – preventing the bad things from happening
- Do the big CMO's have a screening process for which clients they will accept?
- Do pharma co's have a screening process for which contractors they will work with?

Quality Culture

- TRUST – transparency
- Single point of contact – project manager – is it a professional (quality) or is it business or what...
- Role of the QP – influence on quality requirements – US vs EU – differing quality standards? Different requirements
- Highly potent biologic – ants to elephants – our quality standards or theirs

Relationship management

- Quality Agreements – ours or theirs?
- Quality System
- Who's responsible for supply chain and due diligence on that??
- Regulatory inspections
- CFO says “outsource it's cost effective” – but is it and what resources are really needed for ***appropriate oversight and risk management***
- subcontracting

Prevention is about managing risk

- ***Risk management should allow us to identify and triage the high risk outsourced operations and then to manage those risks***
- ***Identifying risks and the associated control mechanisms should allow us to assign appropriate resources***
- If we can introduce a cost of quality / non quality to that model we will have a stronger case for getting resources from management

The initial risk assessment should be by the contract giver

- Risk Factors:
 - Compliance – bad regulatory inspection (potential exposure in terms of: shutdown / recall or other regulatory action)
 - High deviation rate / transparency
 - Technical competencies – do they have the skills set and the facilities to run the project – do they know what they are doing
 - what will be the total cost (overall)
 - Anti – quality culture indicators:
 - Lack of change control
 - Place of quality dept in the organization – who's reporting to whom
 - Documentation practices – time to receive completed batch record
 - Exceedingly low deviation reporting
 - Personnel competency

Communication and key contact

- Have a professional project manager and a quality person and a logistics person and CMC and supply chain and...????
- Have professional who is an SME? Subject matter expert?
- ***PROJECT MANAGER – where are they in the organization and what AUTHORITY do they have in their job description***

Risk assessment tool

- We assign risk to the project based on a formal risk assessment and then we design controls and assign resources for project management

Utilizing outsourced resources in the most efficient manner

- Cooperation
- ***Contract giver – needs to accept the quality system at the service provider – if you don't do that after auditing it – you can't give the contract***

Compromise? Back Up?

RISK MITIGATION

- PIP – person in plant
- Business contract – conflicts with Quality Agreement – internal conflict in my organization before I take it outside to the contractor
- ***Do you have an OUTSOURCING POLICY?*** Sort of? – Managing CMOs

Outsourced Operations Policy (for the Contract Giver / Owner of NDA)

- Risk management
- Legal obligations (especially batch release)
- PIP – authority for that person – SME vs quality vs engineers (decision making / signature authority)
- Resource assignment and management
- Decision making process (process flow) and authority for that / consequences
- Other...