3rd Annual Contract Manufacturing Conference

Conference Agenda

Day One, Tuesday 17th November, 2009

09:30 Registration and refreshments

10:00 Opening address from the chair

Tim Cummins
President
International Association for Contract and Commercial Management (IACCM)

10:10 Globalisation of the contract manufacturing market - a shift from the west to east
• Analysing key trends in the global PCM industry
• Which regions and segments offer the greatest growth opportunities?
• The competitive edge of emerging markets over USA and EU

Sanjit Lamba
President
Eisai (India)

10:50 Outsourcing APIs (advanced pharmaceutical ingredients = active substance) to India: a cheaper way?
• Producing in India: cost, IP, manufacturing experience. Forever green?
• Some consequences on the current market evolution: consolidations, new patent laws in India, decreasing number of NCEs
• New shifts: from API to FDF, from generic drugs to R&D based companies

Laurent Pinchard
Director – EU Operations (API)
Glenmark Generics

11:30 Morning refreshments

11:50 To outsource or not - Is it a solution for you?
• Making the decision to outsource – pros and cons
• Screening process to identify a suitable outsourcing partner
• Set of selection criteria is required to evaluate potential suppliers
• Steps to ensure provision of the deliverables

Debra Nevin
Global CMC and QA Director
Plethora Solutions

12:30EU Requirements for outsourced services (a QP's perspective)
• Legal and regulatory considerations for outsourced manufacture
• Importance of EU GMP
• API vs. medicinal product
• Issues specific to biologics and ATMPs

Bruce Vernon
Director
VYVO BioSolutions

13:10 Networking lunch

14:30 CMO's and SME's: the route to success of a virtual specialty pharmaceutical company
• What is the concept of a virtual pharmaceutical company
• How to outsource all CM&C activities: do's and dont's
• Success drivers of a small company vs. established 'big pharma'
• How to relate with your CMO partners and how not?

Maarten van Geffen
Senior Director CM&C
Movetis

15:10 Designing major pharmaceutical drug dosage forms
• Understanding of the biopharmaceutical factors that influence formulation, manufacture and stability of medicines
• How to develop practical skills and competencies necessary to prepare medicines on a small scale
• What are the issues related to design, manufacture and performance of drug dosage forms
• How to work within the good manufacturing practice (GMP) guidelines

15:50 Afternoon refreshments

16:10 Integration of disposable technologies into process development and clinical trial production
• Use of disposables in the CMO environment
• The journey from development to clinical manufacture
• Novel solutions to novel problems
• Regulatory perspective for disposables
• Future directions for disposables

Daniel Smith
Commercial Scientific Development Manager
Cobra Biomanufacturing

16:50 Think globally, outsource locally
• Does the "one-size-fits-all" approach to outsourcing work?
• When and how to outsource?
• How to develop local strategies to outsource manufacturing?

17:30 Closing remarks from the chair

17:40 Networking drinks
Take your discussions further and build new relationships in a relaxed and informal setting

Day Two, Wednesday 18th November, 2009

09:30 Registration and refreshments

10:00 Opening address from the chair

Tim Cummins
President
International Association for Contract and Commercial Management (IACCM)

10:10 CMOs: A robust growth trend
• What are the key indicators for the growth of CMO business
• Understanding the current market trends and leveraging benefits from it
• What are the commercial implications of increasing globalisation of the API contract manufacturing market

Shiva Khalafpour
Vice President, Europe - Business Development
CMC Biologics

10:50 Challenges of outsourcing biopharmaceutical manufacturing
• Unique features of biopharmaceuticals
• Manufacturing Strategy – in-house or outsource?
• Biopharmaceutical manufacturing capacity constraints
• Emerging opportunities
• Regulatory considerations

Steve Musgrave
Executive Director and co-founder
Unicorn Biologics

11:30 Morning refreshments

11:50 Embracing Quality by Design (QbD)
• Learn on how the FDA is promoting QbD
• Implementing to strengthen the contractor/client relationship
• How to implement Quality by Design to differentiate contractors from competitors
• Using PAT to accomplish real time release/continuous manufacturing

Rebecca Vangenechten
Consultant - Business & Project Development Life Sciences, USA
Siemens Industry & Automation

12:30 Outsourced laboratory compliance and qualification services
• Benefits and advantages of harmonised services
• Meeting regulatory requirements
• Balancing risk and costs through flexibility
• Supporting technology transfer and audits
• A catalyst for change and continuous improvements
• Provisions

Paul Smith
Validation Program Manager (Europe)
PerkinElmer Life and Analytical Sciences

13:10 Networking lunch

14:10 – How to optimise the integration of process development and manufacturing into the biopharmaceuticals development value chain

- Integration of the value chains for drug development and biopharmaceuticals production
- Value of early data acquisition
- Development of scalable and affordable manufacturing processes
- Case studie

Dr. Philipp Gopel
Business Development Manager
Richter-Helm BioTec

14:30 Technology transfer is simple in theory, but difficult in practice
• Understanding different types of transfers
• Formalising the technology transfer procedure
• Allowing scope for future continuous improvements

Nick Hutchinson
Technology Transfer Lead
Lonza Biologics

15:10 Contract packaging is 'not just boxes'
• Choosing the right CMO
• Considerations of pack design/process & reproducibility
• Regulatory considerations – current and future
• Ease of use in the market/patient compliance

David Downey
VP, Commercial Operations
Almac Pharma Services

15:50 Afternoon refreshments

16:10 Leveraging profits through outsourcing in the current economic times
• How to achieve sustained communication and address demand and supply issues to your overseas CMO?
• Understanding the influence of global regulatory culture on establishing outsourcing projects
• Indentifying lucrative opportunities and establishing strategic alliances in emerging markets to minimise costs

Panelist: **Michelle Scott, Executive Director and co-founder, Unicorn Biologics**

16:50 Fitting processes to plant: Balancing flexibility and experience
• Understanding the key manufacturing factors for process design

• Leveraging plant knowledge for efficient manufacture
• Converting learning into continuous improvement

Tarek Abdel-Gawad
Production Manager
Avecia Biologics

17:30 Chair's closing remarks

17:40 End of conference

-Pricing-

- **Standard rate for 3 day pass** - includes the 2-day conference and 1-day interactive workshop - available for only-
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