



EXCLUSIVE ROUNDTABLES

## Exclusive Invitation Only Roundtable Discussion

Date: Wednesday 26th October

Time: 13:30 - 14:30

(followed by 30 minute refreshment break)

Location: Alabaster I & II, Marriott Frankfurt Hotel  
(short walk from ICSE/CPhI)

Panelists Include



Tim Tyson  
Chairman & CEO  
Aptuit



Dr Paul Deutsch  
Senior Director, Chemical Process Development  
UCB Pharma



Dr Alex Robertson  
Director, Sourcing Pharmaceutical Development  
AstraZeneca



Dr Axel Sinner  
Senior Manager Strategy & Operations, Life Science & Healthcare  
Deloitte



Kurt Spekhals  
Senior Director, Pharmaceutical Sciences  
Pfizer



Bayer HealthCare

Ingrid Reinkober  
Vice President Strategic Sourcing Raw Materials & APIs  
Bayer HealthCare

# Outsourcing Non-clinical Early Development

Produced by



Moderated by Jim Miller, President PharmSource



Global bio/pharmaceutical companies have been on a desperate mission to turnaround the productivity of their R&D operations. Executives at the largest bio/pharmaceutical companies have totally re-thought their R&D strategies and restructured their R&D operations to reflect those new strategies.

Greater reliance on outsourcing of R&D is a fundamental part of those new R&D strategies. Outsourcing to CROs is quite advanced in the clinical research arena, where most global bio/pharmaceutical companies have established strategic relationships with a handful of preferred providers. However, outsourcing of non-clinical early development activities, including medicinal and process chemistry, manufacture of clinical materials and GLP toxicology testing, lags well behind clinical research.

The lag in outsourcing of non-clinical development reflects the fact that non-clinical early development activities generate a lot of technical and scientific information about the innovative molecule under development and are more likely to involve an exchange of intellectual property. In addition, outsourcing of non-clinical development may involve closure of existing R&D facilities and staff layoffs, which can generate negative public relations for the bio/pharmaceutical company.

Consequently, the way forward to outsourcing non-clinical early development activities is much less clear and more problematic than for clinical research activities. At the same time, however, the labor intensity of these early development activities make them prime targets for outsourcing, especially to countries with lower human resource costs.

This panel will address some of the key issues facing companies looking to outsource their early non-clinical development, with perspectives from both global and early stage bio/pharmaceutical companies. The issues the panel will address will include:

- The real and imagined obstacles to outsourcing early development
- Best-in-breed versus integrated services models
- Protecting intellectual property
- How to ensure transfer of key scientific and technical insights
- Different issues facing global bio/pharmaceutical companies versus early stage companies
- Dealing with facility closures