

2nd Annual Contract Manufacturing in Pharma 2008

Choosing manufacturing partner for safe, cost-effective operations

*1st - 2nd December 2008, BSG Conference Centre,
London, UK*

Pharmaceutical manufacturers are now withdrawing from manufacturing at an unprecedented rate, with four out of the top 10 players announcing major new outsourcing programs in 2007 - IMS

Outsourcing pharmaceutical manufacturing is now common for Pharmaceutical Manufacturers, both big and small. With the amount of outsourcing increasing the complexity does as well, and it is no simple way of finding the right contractor; something that several pharmaceutical companies have experienced in the past few years.

Besides costs, many other factors has to be considered such as safety, logistics and intellectual property, and choosing the right manufacturer for your needs is not an easy thing to do.

To assist you in this process, visiongain is dedicating its second Contract Manufacturing conference to the different aspects of choosing a contractor such as:

- * The understanding the contract process
- * Different methods of evaluating a contractor
- * Viewing the choice of contractor as a part of a larger strategy
- * Special needs for special manufacturing
- * Choosing a country that satisfies your outsourcing needs

Key Speakers:

- * Tim Cummins, President & CEO, International Association for Contract and Commercial Management (IACCM)
- * Martin Grosvenor, Drug Delivery Manager, AstraZeneca
- * Scott Coward, Partner, Kennedy Covington Lobdell &

Hickman

- * Craig Thomson, Attorney, Murgitroyd & Company
- * Professor Nigel Titchener-Hooker, Deputy Head of Biochemical Engineering, University College London
- * Stephen Hammond, CEO, Scottish Biomedical
- * Mitch Rogers, Business Development Manager, Health Protection Agency
- * Wieland Wolf, Member of the board, Rentschler
- * Debra Sponholtz, Director, Business Development, Chembiotek Research International
- * Udo Quotschalla, Global Head of NCE Process R&D, UCB, Belgium
- * Gary Montague, Professor of Bioprocess Control, University of Newcastle
- * Karen MacGregor, Director, Project and Contract Management, Europe, Catalent

Who will be there?

VPs Directors, Heads, and Managers in:

- * Manufacturing
- * Production
- * CMC
- * Procurement & Purchasing
- * Outsourcing
- * Operations
- * Strategic Alliances
- * Clinical Product Resourcing or Supply
- * Contract Management
- * Process Development
- * Supply Chain
- * R&D Manufacturing
- * Business Development
- * Quality Management
- * Regulatory Affairs

Sponsorship and exhibition opportunities:

If you would like benefit by promoting your organisation at one of our events then exhibiting is perfect for you.

- Network with industry decision-makers
- Increase and maintain brand awareness
- Meet potential clients face to face
- Target your marketing campaign
- Present your latest products and ideas

I look forward to meeting with you at the event.

- PRICING -

- 2 day Conference ticket - available for only **GBP £1299**

Places at this conference are limited and are issued on a strict first come, first served basis.

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Payment Method - INVOICE or CREDIT CARD details

You can either email me at

pharma.conferences1@conferencesandreports.com or

call on TEL: +44 (0)207 549 9971.

Kind regards,

Jacob Samek

[Visiongain Ltd.](#)

4th Floor,

BSG House,

226-236 City Road,

London

EC1V 2QY

United Kingdom

Conference Agenda

Day One, Monday, 1st December 2008

09:30 Registration and refreshments

10:00 Opening address from the chair

Tim Cummins

President & CEO

**International Association for Contract and
Commercial Management (IACCM)**

**10:10 When is outsourcing of manufacture the right
choice?**

* Outsourcing - help or hindrance?

- * Examples of what to outsource
- * Do I have enough time for outsourcing?
- * Value benefits and their measurement
- * Learning review of experience - a one-off or repeatable event?

Martin Grosvenor
Drug Delivery Manager
AstraZeneca

10:50 Outsourcing research and development, and active pharmaceutical ingredients

- * Rationale of outsourcing: why is outsourcing an option at all?
- * Different levels of outsourcing: what kind of services at which state of the process could make sense?
- * Key factors of a successful collaboration
- * Quality and compliance level required
- * Case study examples of efficient development

Udo Quatschalla
Global Head of NCE Process R&D
UCB, Belgium.

11:30 Morning refreshments

11:50 Understanding contracts and the contracting process

- * Contract fundamentals- what constitutes a binding, legal contract?
- * The contracting process- getting to 'yes'
- * Key terms of an outsourcing contract including: Minimums, Exclusivity, IP, and Indemnification

Scott Coward
Partner
Kennedy Covington Lobdell & Hickman

12:30 Contract manufacturing and IP legislation

- * How intellectual property legislation relates to contract manufacturing
- * How can IP-legislation be a factor when choosing a contractor?
- * Case studies

13:10 Networking lunch

**14:30 IP Ownership Issues in a Contract
Manufacturing Relationship**

- * Problems associated with not addressing ownership of IP early in the relationship
- * How the law can help to avoid these problems
- * Is there any reason to share IP?

Craig Thomson
Attorney
Murgitroyd & Company

15:10 A checklist for outsourcing in the UK

- * Discussing the rules and regulations that applies specifically to the UK
- * Using UK regulations in the evaluation process
- * UK compared to other countries

Paul Ranson
Partner
Fasken Martineau Stringer Saul

15:50 Afternoon refreshments

**16:10 Evaluating safety aspects in contract
manufacturing**

- * Discussing relevant safety aspects
- * Evaluation tools and how to use them
- * The necessity of safety aspects when choosing a contractor

**16:50 Ensuring cost-effective operations in a changing
world**

- * New rules of engagement
- * How to keep up
- * How to evaluate the cost effectiveness in a ever changing worlds

Karen MacGregor
Director, Project and Contract Management
Europe, Catalent

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, Tuesday, 2nd December 2008

09:30 Registration and refreshments

10:00 Opening address from the chair

**Professor Nigel Titchener-Hooker
Deputy Head of Biochemical Engineering
University College London**

**10:10 Outsourcing process research and development,
and active pharmaceutical ingredients**

**Udo Quotschalla
Head of Chemistry
Schwarz Biosciences GmbH.**

**10:50 Choosing the right partner to produce your
recombinant protein**

- * Getting the right recombinant clone, vector + host to express your protein
- * Scaling up to obtain sufficient yields
- * Purification strategies + QC
- * What to look for when choosing a partner

**Stephen Hammond
CEO
Scottish Biomedical**

11:30 Morning refreshments

**11:50 Addressing issues surrounding high containment
manufacturing**

- * Understand the process
- * Identify the risk
- * Manage the risk

**Mitch Rogers
Business Development Manager
Health Protection Agency**

**12:30 New opportunities as a consequence of FDA, PAT
and QbD initiatives**

- * PAT and QbD: what it means to CMOs

- * Tools to exploit the data that PAT provides
- * Steps in achieving quality by design

Gary Montague
Professor of Bioprocess Control
University of Newcastle

13:10 Networking lunch

14:30 Choosing the right country for your outsourcing needs

- * How to evaluate contractors dependent on their location
- * Discuss the competitiveness of different markets
- * How to ensure the country is right for your needs

Wieland Wolf
Member of the board
Rentschler

15:10 Considering India

- * Examining appropriate decision component when considering India
- * Discussing potential obstacles
- * Rules and regulations

Debra Sponholtz
Director, Business Development
Chembiotek Research International

15:50 Afternoon refreshments

16:10 India's advantages in contract R&D and manufacturing

- * Looking at innovation, speed, quality and competitive costs
- * How to solve the supply chain
- * Discussing the evaluation process

16:50 Choosing a CMO in Eastern Europe

- * Looking at the opportunities in eastern Europe
- * Competitiveness and cost-effectiveness
- * Supply chain issues

17:30 Chair's closing remarks

17:40 End of conference

List of upcoming events

You might be also interested in attending other events organised by **Visiongain**. Below you can find list of these events.

If you would like to receive more information on a selected event do not hesitate contacting me.

7th Annual Pricing & Reimbursement

30th September - 1st October 2008, London, UK

Pain Management 2008

7th - 8th October 2008, London, UK

Colloquium on Obesity Drug Development

13th - 14th October 2008, London, UK

Workshop on In Vitro-In Vivo Correlation (IVIVC)

14th October 2008, London, UK

Clinical Trials in India and China

22nd - 24th October 2008, London, UK

Drug Formulation Technologies

4th - 5th November 2008, London, UK

4th Biosimilars

11th - 13th November 2008, Philadelphia, USA

P53 Strategies for fighting cancer

20th - 21st November 2008, London, UK

Re-emerging infectious diseases

11th - 12th December 2008, London, UK

2nd Cold Chain

19th - 21st January 2009, London, UK

2nd Annual Smoking Cessation 2009

26th - 27th January 2009, London, UK

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