

**4th INTERNATIONAL FORUM
ON BUSINESS DEVELOPMENT IN APIs & GMP FINE CHEMICALS**

31st March - 1st April 2008

Fairmont Monte Carlo Hotel, 12 Avenue des Spelugues, Monaco



FORUM PROGRAMME - MONDAY 31st MARCH 2008

08:00 - 09:00 Registration & Welcome Networking Coffee

09:00 - 09:45 Introduction and general overview of the industry

- Major events and developments affecting the industry
- Regulatory changes and industry reactions
- Mega-trends

Paolo Romagnoli - President Romagnoli Consulting

09:45 - 10:30 What is the future for API Brokers?

Positive Trends

- One BE Study for US and EU will increase sales faster
- Abbreviated Biogenerics USA Pathway opens up segment
- New companies need API brokers
- Are there any other positive trends?

Negative Trends

- Increasing Backward Integration
- Higher EU prices for Generics vs. USA will limit USA API Brokers
- Frequent waiving of up-front dossier fees limits pricing flexibility
- EU price drops squeeze API suppliers
- Many other negative trends will be presented

Richard DiCicco - President Technology Catalysts

10:30 - 11:00 Coffee Break

11:00 - 11:45 The woes of the pharmaceutical industry - the impact on the fine chemicals industry

- The pharmaceutical industry is suffering from low research productivity and a high product attrition rate
- It is reacting by implementing manufacturing restructuring programs
- This results in more outsourcing of chemical manufacturing to fine chemical companies
- Both Western and Asian companies will benefit from this new trend


Peter Pollak - Fine Chemicals Business Consultant

11:45 - 12:30 Anticipating and adapting to major market changes: a variety of solutions

- The pharmaceutical industry is and will be experiencing many dramatic changes
- What consequences for fine chemical suppliers?
- What are the new business models for growth?
- Zach System, a specific solution

Jean-François Marcopoulos - General Manager Zach system

12:30 - 14:00 Networking Buffet Lunch

- 14:00 - 14:45 **U.S. Litigation update - Recent developments**
- Increasing number of settlements and the strategies surrounding them
 - Reversals on Appeal
 - Direct and indirect infringement
 - The changing role of attorney opinions
 - Declaratory judgments
- Neil Greenblum - Managing Partner Greenblum & Bernstein
- 14:45 - 15:30 **IP: The view from industry**
Zeynep Ulusoy - Deputy General Manager Technical Divisions Nobel İlaç San. ve Tic. A.Ş.
- 15:30 - 16:00 **Questions & Answers**
- 16:00 - 16:30 **Coffee Break**
- 16:30 - 16:50 **Latest EU developments affecting starting materials**
- Revision of the EU GMP Guide
 - Impact of the ICH Quality related topics
- Julie Maréchal, Senior Manager Regulatory Affairs European Generic medicines Association (EGA)
- 16:50 - 17:25 **How to increase sales of APIs**
- Forward integrate to finished dosage forms
 - Partner with finished dose backward integrated dossier brokers
 - Increase and maintain quality while lowering cost of goods
 - Improve margins through hospital market customers
- Ineke Braat, Managing Director of Pan-Generika
- 17:25 - 17:45 **Questions & Answers**
- 18:00 - 20:00 **Networking Buffet Dinner sponsored by  MaltaEnterprise**

FORUM PROGRAMME - TUESDAY 1st APRIL 2008

- 09:00 - 09:45 **Demand perspectives**
Graham Lewis - Vice-President Europe Pharma Strategy IMS Health
- 09:45 - 10:30 **The buck stops in China**
Rob Bryant, Brychem
- 10:30 - 10:45 **Question & Answers**
- 10:45 - 11:15 **Coffee Break**
- 11:15 - 11:45 **The evolving role of Indian API companies in the regulated markets**
- Lifecycle of API industry
 - India advantage
 - Changing scenario of Indian API players in advanced markets
- Vikas Narendra - President ISL INC.
- 11:45 - 12:30 **Generic Industry backward integration: Does it make sense?**
- Examples and strategies
 - The meaning, impact and cost of the vertical integration
 - Pros and cons
- Paolo Romagnoli - President Romagnoli Consulting
- 12:30 - 13:00 **Round table discussion with speakers and Q&A session**
- 13:00 - 14:30 **End of Forum and Light Buffet Lunch**



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