



**1st INTERNATIONAL FORUM
ON BUSINESS DEVELOPMENT
IN API & GMP FINE CHEMICALS**

21-22 February 2005

**Sheraton Roma
Viale del Pattinaggio 100
I-00144 Rome**

MONDAY 21 FEBRUARY 2005

08:30 - 09:15 Registration & Welcome Coffee

**Section 1: The Industry, General business environment, Demand, Offer.
Co-Chaired by Paolo Romagnoli & Guy Villax**

09:15 - 11:00

Industry definition, key issues, segments, structure

- Industry characteristics
- Market and competition components
- The general business environment
- The meaning of business development
- Selecting and managing new projects

Paolo Romagnoli - Angelini Fine Chemicals, Italy & Spain

The international market scenario and perspectives

- Impact of cost containment on generic growth
- Volume and value forecasts to 2008
- Future generic blockbusters: winners and losers

Graham Lewis - IMS Health, UK

Q&A

11:00 - 11:30 Networking Coffee Break

11:30 - 13:00

New challenges for the manufacturers

- Impact of the gap between Italian and European SPCs
- Price of API vs quality
- The role of CEP; the failure of a chance
- Rules are necessary; but for all competitors

Alberto Mangia - Poli Industria Chimica SPA & President CPA, Italy

Why Fine Chemicals Business Development has Failed?

- Business Development of the Fine Chemicals Industry has failed to convince the Pharmaceutical Industry of the advantages of outsourcing, despite
 - an increasing demand for API & GMP fine chemicals
 - a perfectly tailored offering
- ... and the industry is suffering from declining sales and profits

Peter Pollak - Fine Chemicals Business Consultant, Switzerland

Q&A

13:00 - 14:30 Buffet Lunch

Section 2: Regulatory, Legal and Technical issues.
Co-Chaired by Greg Perry, EGA & Paolo Romagnoli

14:30 - 16:00

The US legal framework affecting the generic industry and its suppliers

- Process patents: infringement and obtaining information from the patent owner
- Introduction to the ANDA (generic drug application) process
- The certification process

Neil Greenblum - Greenblum & Bernstein, USA

International Intellectual Property Rights

- Diversity of API Patents - Not just process patents
- Third Party API Patents - An increasingly important issue
- API Patent Infringement - Opinions, Litigation, Tactics and more

Yehudah Livneh - TEVA, Israel

Q&A

16:00 - 16:30 Networking Coffee Break

16:30 - 18:00

API requirements in the context of generic registrations in Europe

- What is going to change in November 2005?
- How are GMP requirements being endorsed?
- Are API inspections becoming a bottleneck for registrations?

Suzette Kox - European Generic medicines Association (EGA), Belgium

The new technological challenges

- new substance classes (e.g. Oligo's and RNAi) and new technologies (e.g. enzymatic and catalytic reactions; microreactors)
- high potency substances and hazardous chemistry
- biologicals and biogenerics

Prof. Dr. Axel Kleemann, Germany

GMP issues: international development and enforcement: CEP as an example Agnès Artiges - Director EDQM (Council of Europe), France

Q&A

18:30 - 20:00 Networking Light Buffet Dinner

TUESDAY 22 FEBRUARY 2005

Section 3: Marketing and Business Development.
Co-Chaired by Paolo Romagnoli & Guy Villax

09:15 - 10:45

Business Development and distribution in the USA

- A new role for agents & distributors
- Identifying & selecting opportunities
- Tactics & market approaches

Paolo Romagnoli - Angelini Fine Chemicals, Italy & Spain

APIs for the European Generic Industry. Sourcing issues

- Bolar... will it put European plants back on the API map?
- Certificates of Suitability...a real advantage for API manufacturers?
- Inspections and Compliance

Howard Rosenberg - Merck Generics, UK

Q&A

10:45 - 11:15 Networking Coffee Break

11:15 - 13:00

Challenging accepted truths

- There is no Bolar provision in Europe - wrong
- API firms cannot develop special relationships with Generic Houses - wrong
- Generics are a quick fix for new entrants from the fine chemical's industry - wrong
- Large Pharma are lowest cost producers of APIs - correct
- FDA inspections are getting easier - wrong

Guy Villax - CEO Hovione, Portugal

Outsourcing policies and strategies for NCEs

- Overview of current NCE Pharma landscape
- Outsourcing Strategies: Big Pharma vs. Virtual/Biotech
- Maximizing marketing effectiveness vs. opportunities

Gary Conte - Charkitchchemical Corp., USA

Integrated distribution in Europe

- APIs' new ways to the generics market
- Opportunities and challenges for API manufacturer
- Adding the value

Gerhard Schneider - Alfred E. Tiefenbacher, Germany

13:00 End of Conference & Light Buffet Lunch



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