

## Topics

### Outsourcing Outlook & Challenges

- ◆ Outsourcing by Ethical Pharma Companies
- ◆ Outsourcing by Generic Pharma Companies
  - Change in the Pharma Industry- What it Means for the Supply Chain
  - Arranging Clinical and Biostudies for Medicines and Medical devices
  - Contracting with Indian and Chinese CROs – Challenges and Opportunities
  - The Role of China in Drug Discovery in the 21st Century: A View From the Starting Gate
  - Outsourcing of Clinical APIs: Is China Ready?
  - Drug Discovery and the Importance of Outsourcing
  - Introducing generic APIs to the Highly Competitive North American Market



## Speakers :

Dr. Simon Sellers, CEO, Bioavailability Systems LLC (USA)

Mr. Max Zive, President, Zipharm International Inc (Canada)

Dr. Jay Reddy, Vice President, Sai Advantium Pharma Limited

Dr. Kerry Spear, Executive Director, Sepracor Corporation (USA)

Dr. James J. Chen, President & Founder, Agno Pharma (USA)

Dr. Bill Purcell, President & Chief Manager, Concert LLC (USA)

Mr. Aviv Laor, Director, Azad Fine Chemicals (Switzerland)

*to be continued.....*

# 4<sup>th</sup> ANNUAL CONFERENCE ON PHARMACEUTICAL OUTSOURCING

## Time:

17-18 April 2008

## Venue:

Jian Su Nanjing, P.R China (waiting for confirmation)

## Organisation:

Beijing Orientbit Technology Ltd(healthoo.cm)

Agno Pharma (USA)

## Language

Conference language

The official conference language will be both English and Chinese.

## ABOUT OUR EXPERT SPEAKERS



**Speakers:** Dr. Simon Sellers, CEO,  
Bioavailability Systems LLC (USA)

Dr. Sellers has managed pharmaceutical chemical supply-chain businesses for Great Lakes, Sumitomo Chemical, Catalytica Pharmaceuticals and BTP. He has a PhD in chemistry and spent fifteen years working as a process development chemist before moving into management. He is currently CEO of Bioavailability Systems, LLC- an emerging biopharmaceutical company developing combination drugs with enhanced oral bioavailability. He also consults for the chemical and pharmaceutical industries.

### Change in the Pharma Industry- What it Means for the Supply Chain

**Abstract:** Shrinking pipelines, poor return on R&D investment, loss of patent protection on key products, regulatory, political and investor pressures are all leading to a major shift in the business management of large pharmaceutical companies. Implications for the global supply-chain will be examined.



**Speakers:** Dr. Bill Purcell, President & Chief  
Manager, Concert LLC (USA)

William P. Purcell, Ph. D., the founder and majority shareholder of CONCERT, LLC and serves as its President. Dr. Purcell has had a distinguished career as a Professor of medicinal Chemistry at The University of Tennessee (Memphis) and currently serves as an adjunct member of the Graduate Faculty, Department of Chemistry, at the University of Memphis.

Dr. Purcell is a recognized expert in the field of molecular modeling and is a pioneer in Quantitative Structure-Activity Relationships (QSAR) with his book, a first in this area, entitled "Strategy of Drug Design: A Molecular Guide To Biological Activity" (John Wiley and Sons, New York, 1973).

Dr. Purcell is co-founder of the quarterly publication QSAR Including Molecular Modeling and Applications of Computer Graphics. He has regularly contributed articles on the application of QSAR techniques to drug design and development to scholarly publications, including Journal of Medicinal Chemistry, Journal of Pharmaceutical Sciences, and Molecular Pharmacology.

He is an inventor of a number of U.S. and foreign drug patents. Dr. Purcell has an AB degree in Chemistry from Indiana University and AM and Ph.D. degrees in Physical Chemistry from Princeton University.

### Drug Discovery and the Importance of Outsourcing

**Abstract:** In today's world of the discovery of new molecules for pharmaceutical and cosmetic application, multidisciplinary expertise is needed to complete the process from discovery to the marketplace. CONCERT is a small cosmetic discovery company with unique and proprietary molecules that are effective and safe as cosmetic ingredients. In order to manufacture these compounds and to reach competitive cosmetic markets, CONCERT must look to resources beyond its usual domestic avenues. This presentation will describe the search for interdisciplinary resources to accomplish CONCERT goals and objectives.



**Speakers:** Dr. Jay Reddy, Vice President,  
Sai Advantium Pharma Limited

Dr. Jay Reddy is a Vice President at Sai Advantium Pharma Ltd managing the Process and Analytical R&D functions. Jay received his BSc from University of Madras (India), his PhD from The University of Kansas and was a post-doctoral fellow at Indiana University. Over the 14 years he has been in the industry, his career has been spent at Bristol-Myers Squibb, AMRI, Neurocrine Biosciences and Takeda where he managed several projects in development and in various stages of manufacturing. Also, Jay helped start a company called American Advanced Organics, a CRO that merged with AMRI and became the Syracuse Research Center in 2000.

### Contracting with Indian and Chinese CROs – Challenges and Opportunities

**Abstract:** Abstract: Challenges faced by a biopharma or pharma client in dealing with typical CROs in India and China will be discussed. With a critical look at relationships between clients and contractors, opportunities for improvement will be presented.



**Speakers:** Dr. Kerry Spear, Executive  
Director, Sepracor Corporation (USA)

Dr. Spear is Executive Director of Medicinal Chemistry at Sepracor, a pharmaceutical company headquartered in Marlborough, MA, USA. He is currently in charge of all medicinal chemistry efforts within Sepracor's Discovery Research Department. Trained in natural products synthesis, he has over 25 years of experience as a medicinal chemist in both the pharmaceutical (e.g., G.D. Searle) and the biotechnology (e.g., Chiron) industries. He has participated in or led programs that cover a broad range of drug discovery research and which have resulted in the acceptance by the FDA of 7 IND applications. Dr. Spear completed a postdoctoral fellowship at the University of California, Berkeley. He received a Ph.D. degree in organic chemistry from the University of Wisconsin, Madison and a B.S. degree in chemistry from Juniata College.

### The Role of China in Drug Discovery in the 21st Century: A View From the Starting Gate

**Abstract:** In less than a decade, outsourcing of some aspects of pharmaceutical research to Asia has emerged as an integral part of Pharma's drug discovery strategy. While these efforts initially focused on compound synthesis, recently CROs in China have begun adding in vitro and in vivo biology proficiencies to compliment their core strengths in chemistry. Additionally, by building a deeper leadership pool, these CROs are now poised to contribute drug discovery expertise and knowledge as well as fundamental chemistry and biology skills. These additional capabilities offer new and broader opportunities for partnering with Chinese CROs in order to accelerate drug discovery efforts and control costs. Efforts to integrate chemistry and biology resources within Chinese CROs with ongoing drug discovery efforts at Sepracor will be discussed.



**Speakers: Dr. James J. Chen, President & Founder, Agno Pharma (USA)**

Dr. Chen is currently President of Agno Pharma, an international pharmaceutical contract research and manufacturing company engaged in providing cGMP product development and API manufacturing services to both branded and generic pharmaceutical companies mainly in North America. In addition, Agno Pharma represents many reliable Chinese API manufacturers in registering and selling their products in North America. Dr. Chen has 15 years of pharmaceutical development & commercialization experience with both API and finished pharmaceutical products. His current responsibilities include setting corporate directives and strategies as well as developing strategic business partnership and alliance with clients and partnering suppliers. Dr. Chen has given numerous lectures in the area of "GMPs for APIs", "CMC Regulatory Submissions and Requirements" and "Outsourcing APIs to China" in major US and Canadian cities. Prior to founding Agno Pharma, Dr. Chen was employed by the DuPont Merck Pharmaceuticals Company (now Bristol-Myers Squibb) and Schering-Plough Corporation. Dr. Chen published more than 20 research publications, including review articles and book chapters, and has given numerous podium presentations at national scientific, compliance and outsourcing meetings. Dr. Chen holds a Ph.D. in Chemistry from University of Pittsburgh, an DuPont Merck sponsored MBA from University of Delaware and a B.Sc. from State University of New York at Stony Brook.

**Outsourcing of Clinical APIs: Is China Ready?**

Abstract: India and China have been the major beneficiaries of outsourced pharmaceutical intermediates and generic APIs by North American clients. Due to competitive pressure, many North American clients have started to outsource clinical APIs and generic dosage forms, particularly to Indian CROs & CMOs. Clinical APIs involves more stringent intellectual property protection and higher degree of client services as compared to generic APIs. Is China ready to capitalize this high value-added business from North American clients? This presentation will provide unbiased perspectives on this topic.



**Speakers: Mr. Aviv Laor, Director, Azad Fine Chemicals (Switzerland)**

Aviv Laor has been involved in the heart of the generic business for the past 15 years. He has studied, selected, managed the development of, and marketed many APIs in North America, Europe, and the Middle East. Mr. Laor has gathered experience in marketing simple molecules to highly complex Paragraph IV challenges. In addition to APIs, Aviv is also involved in the marketing of Finished Dosage and value added generics.

Mr. Laor is a graduate of Concordia University and lives in Montreal Canada with his family.

**Introducing generic APIs to the Highly Competitive North American Market**

Abstract: Planning to introduce Generic APIs to the North American market involves many considerations. This presentation will go over key deliberations such as understanding where the market is headed, where your clients are going, and how you are perceived. In addition, we will look at positioning your line of products, patent considerations, revenue timing, and customer relations. By the end of the presentation the audience will get a better sense of what it takes to plan for the North American future.



**Speakers: Mr. Max Zive, President, Zipharm International Inc (Canada)**

A pharmacist by profession, Max Zive resides in Toronto, Canada and has extensive pharmaceutical experience in North America and internationally.

He presently serves as President, of Zipharm International Inc, a company he founded in 1998 specializing in:

- Regulatory Affairs
- Business Consulting Services
- R&D Projects
- Marketing of Pharmaceuticals, Medical Devices
- Pharmaceutical Formulation and Product development
- Registration of pharmaceuticals, medical devices and herbal medicines
- Organizing and providing educational "certification courses" e.g. Regulatory Affairs; Manufacturing Operations; Quality Control (Laboratory); Quality Assurance etc.

**Arranging Clinical and Biostudies for Medicines and Medical devices**

International distribution network.

Early in his career, Mr. Zive was instrumental in establishing, Genpharm Inc, a company that was to become one of Canada's leading generic drug manufacturers and distributors generating sales over \$450,000,000 per annum before merging with E.Merck of Germany in the 1990's. As one of the company's first Presidents, he established "state of the art" pharmaceutical manufacturing facilities, analytical laboratories and an R&D centre. He also oversaw clinical and bio studies for newly developed drugs.

**Registration**

Via the reservation form, by e-mail or by fax message. Or you register online at

[http://www.healthoo.com/new\\_site/gjlt\\_4/bmfs\\_zygjlt.asp](http://www.healthoo.com/new_site/gjlt_4/bmfs_zygjlt.asp)

Download Reservation Form

Please contact Ms Wu, and Mr. An wenhua

Phone + 86-10 68032463 Fax +86-10 68052505

Email [anwh@healthoo.com](mailto:anwh@healthoo.com) ; [wuhf@healthoo.com](mailto:wuhf@healthoo.com)

**Fees**

2880 RMB each or 480 US \$ each

The registration fee is payable in advance after receipt of invoice.

Bank information

Receiver : Orient Health Ecommerce Ltd

Number Account : 110060239018002127366

Bank Name : Bank of Communications Beijing Branch , Fuwai Sub-Branch

Bank Address : No7, Fuwaistreet, Xicheng District, Beijing, China

Swift Code : Comcnshbjg

**Cancellation**

If you have to cancel entirely, we must charge the following processing fees:

- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

## SPONSOR BRIEF INTRODUCTION

### Orientbit Technology Co.,Ltd.

The "www.healthoo.com" Web is an internet information serving plain-plat in pharmaceutical & medical industry, which is setup by the Orient Health Electronic Commercial Company in June 1996. At the time of developing and exploring different channels effectively, it devoted into the professional information consulting, which covered from APIs, pharmaceutical product to terminal distribution. It provides the dynamic distribution analysis and market evaluation on six blocks: chemical drugs, Chinese drugs, health food, animal health production, medical treatment instrument and biological pharmacy, which is helpful for customers to grasp the economic, policy and research information. In order to support the domestic and foreign enterprises in strategy decision, it cut down the cost of information collecting and processing, improved its availability, enlarged market share and extended distribution channels.

The service ways of the Health Web included internet member system, market research, industry report and import & export reports. Now we already possess 500 members and 2000enterprises including Chinese 100 top corporations, large companies and international firms. The goal of the company is to setup the best information service brand in China and act as a protagonist in the pharmaceutical industry stage.

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### Agno Pharma (USA)

Agno Pharma is a US-based leading international contract research and manufacturing company focuses on providing pharmaceutical research, development and manufacturing services of intermediates and APIs. Our company is founded upon our belief in the synergistic merger of North American pharmaceutical technologies, management, product registration, cGMP compliance with China's economical development and manufacturing capabilities. This North America-China synergy allows us to provide the highest quality services and products to our North America & European clients in a timely manner that is extremely cost competitive. Agno Pharma is a US FDA-registered company and holder of DMFs in CTD format. Our cGMP facility is fully compliant with ICH Q7A requirements and our non-GMP facility is ISO-certified. All members of our senior management team have many years of work experience for multinational pharmaceutical companies prior to joining Agno Pharma. All members of our organization are fully committed to quality and compliance. To better serve our clients, we have partnered with several reliable North American and Chinese clients, suppliers and market research organizations. This allows us to provide sourcing, consulting and licensing services for our clients worldwide.

Agno Pharma is a member of the Synthetic Organic Chemical Manufacturers Association (SOCMA) and DCAT (Drug, Chemical & Associated Technologies). We honor and practice ChemStewards' core principles to ensure all our services and products are environmentally friendly.

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### 4<sup>th</sup> ANNUAL CONFERENCE ON PHARMACEUTICAL OUTSOURCING (China)

#### Registration

Via the reservation form by e-mail or by fax message.

Or you register online at [http://www.healthoo.com/new\\_site/gjlt\\_4/bmfs\\_zygjlt.asp](http://www.healthoo.com/new_site/gjlt_4/bmfs_zygjlt.asp)

Please contact Ms Wu, and Mr. An wenhua

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email [anwh@healthoo.com](mailto:anwh@healthoo.com) [wuhf@healthoo.com](mailto:wuhf@healthoo.com)

#### Reservation Form

Mr  Ms Title \_\_\_\_\_

First name, surname \_\_\_\_\_

Company Department \_\_\_\_\_

Street / P.O. Box \_\_\_\_\_

City Zip Code Country \_\_\_\_\_

Phone / Fax \_\_\_\_\_

E-mail (please fill in) \_\_\_\_\_

#### Book Hotel

Four-star  Single Bed  Double Bed  A suite

Five-Star  Single Bed  Double Bed  A suite

No