

MEDICAL AFFAIRS | SEMINAR

Launching a High-Value Medical & Scientific Affairs Team

*State-of-the-Art Capability in Establishing/Growing
Medical Affairs or Scientific Affairs Departments*



JANUARY 22-23, 2013

Omni Parker House
Boston, MA

COURSE LEADER

Shahin Gharakhanian, MD, DPH
*Former, Vice President, Global Medical
Affairs, VERTEX PHARMACEUTICALS, INC.,
Member of the Executive Committee,
ASSOCIATION OF MEDICAL AFFAIRS'
PROFESSIONALS (AMAP), Principal &
Founder, SHAHIN GHARAKHANIAN
MD CONSULTING LLC*

GUEST EXPERTS

Tyke White, BS, MBA
*Senior Director of Medical Alliances,
Global Medical Affairs
VERTEX PHARMACEUTICALS*

Thomas Gesell, PharmD
*Medical Affairs Leader
ENVISION TECHNOLOGY SOLUTIONS*

Purohit Prakash, PhD
*Head of Scientific Affairs US/NA
IPSEN PHARMA*

Barry Lubarsky, PhD
*Director, Medical Affairs
VERTEX PHARMACEUTICALS*

Paula D. Leca
*General Counsel
NEW YORK GENOME CENTER*

FEATURED TOPICS COVERED:

- » Cross-Functional Collaboration:
Who, How, and Why?
- » Phenotypes of Successful Medical Affairs Hires
- » How to Create and Successfully Implement
a Medical Plan
- » Medical Affairs Metrics...The Holy Grail?
- » Tying it All Together - Medical Affairs as a
Living Organization

MEET-THE-EXPERT SESSIONS COVERING

- » Establishing a Compliant Medical Affairs
Department
- » Medical Affairs Team Building:
- » Medical Affairs Information Systems (IS):
Opportunities/Challenges

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CELGENE CORPORATION

"Thought-provoking and engaging presentation,"

— Robert Garris, Associate Medical Director, Actelion Pharmaceuticals

DEAR COLLEAGUE,

During the past decade, Medical Affairs or Scientific Affairs have become a critical function within all pharmaceutical and biotechnology companies. While these two terms are used interchangeably some companies define these differently. A high-performance Medical or Scientific Affairs team will not only support but drive the safe, effective and appropriate use of medications and contribute to product lifecycle. A Medical or Scientific Affairs Department is now a necessity rather than a luxury.

"Launching a High Value Medical Affairs or Scientific Affairs Team" is an interactive learning opportunity for professionals who are setting up, expanding or restructuring Medical Affairs Departments and Groups. This program will help participants identify the needs of their organization, the appropriate structure and organizational alignment and identify critical functions, and will clarify many other operational aspects that are key to building a sustainable and respected department. This conference will offer an opportunity to learn from others who have built Medical Affairs teams from the ground up, including the good, the bad and the ugly! Finally, and most important, the program is an excellent opportunity to pause from everyday duties, in order to reflect on your medical affairs strategies and tactics, and exchange experiences through networking and discussion with your peers and guest experts.

Looking forward to your participation,

Sincerely,

Shahin Gharakhanian

SHAHIN GHARAKHANIAN MD, Course Leader,
Former, Vice President, Global Medical Affairs, Vertex Pharmaceuticals, Inc.,
Cambridge MA, USA, Member of the Executive Committee, Association of Medical
Affairs' Professionals (AMAP), Principal & Founder, Shahin Gharakhanian MD
Consulting LLC, Cambridge MA, USA.

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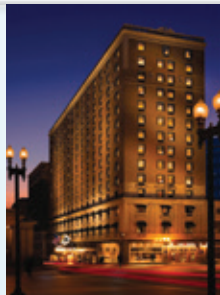
This conference is of interest Pharmaceutical, Biotechnology, Specialty, Medical Device, CRO and Service Providers with responsibilities in:

- Medical Affairs/Field Medical Affairs
- Scientific Affairs
- Medical Directors/Strategy
- Research & Development
- Medical Science Liaisons
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HOTEL INFORMATION

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DAY ONE

LAUNCHING A HIGH-VALUE MEDICAL/SCIENTIFIC AFFAIRS TEAM TUESDAY, JANUARY 22, 2013

8:00 Registration Opens & Continental Breakfast – Delivery of course materials

9:00 **Chairperson's Day One Welcome and Introductions**
Shahin Gharakhanian MD, *Principal & Founder*, **SHAHIN GHARAKHANIAN MD CONSULTING LLC**

Defining the Roadmap

9:15 **Does Your Organization Know Why it Needs to Establish or Grow Medical Affairs?**
Introduction: A Critical Role for Medical Affairs, Now and In the Future

- The ultimate goal is to improve patient care
- The role of Medical Affairs in key areas including:
 - o NDA processes
 - o New Drug Launches
 - o Lifecycle Management
- Recognition of Medical Affairs:
 - o Organization charts
 - o Senior management
 - o Within the Healthcare Provider community

Shahin Gharakhanian MD, *Principal & Founder*, **SHAHIN GHARAKHANIAN MD CONSULTING LLC**

9:45 **Does Your Organization Agree on What Medical Affairs Should be?**

Defining your Organization's Need for Medical Affairs

- Perform organizational inventories
- Explore unmet medical needs for your organization using a top-down or bottom-up approach
- Identify opportunities for Medical Affairs in company functions
- Align the role Medical Affairs will play with your organization's needs and orientation

Tyke White, BS, MBA, *Senior Director of Medical Alliances, Global Medical Affairs*, **VERTEX PHARMACEUTICALS**

10:15 **Networking & Refreshment Break**

10:45 **What Do You Need to Get Started?**
Determine the Mandate and Identify Resources

- Senior management consensus and mandate
- Internal human resources & stakeholders
- External resources: agencies, consultants, software, specialized vendors
- Reports, bibliography, documents, journals
- Professional meetings and associations

Shahin Gharakhanian MD, *Principal & Founder*, **SHAHIN GHARAKHANIAN MD CONSULTING LLC**

Tyke White, BS, MBA, *Senior Director of Medical Alliances, Global Medical Affairs*, **VERTEX PHARMACEUTICALS**

Defining the Structure

11:15 **Positioning of Medical or Scientific Affairs within the Organization?**

Cross-Functional Collaboration: Who, How, and Why?

- Identify key teams, meetings, working groups where Medical Affairs has a place
- Establish Medical Affairs-owned meetings
- Identify ways to become a strong cross-functional partner

Purohit Prakash PhD, *Head of Scientific Affairs US/NA*, **IPSEN PHARMA**

11:45 **Determine the Optimum Structure and Organizational Placement for Medical Affairs**

- Pros and cons of different models for Medical Affairs structures and placement
 - o Free-standing?
 - o Clinical Development?
 - o R&D?
 - o Other options?
- The inclusion of Medical Affairs representation in various corporate teams
- Reporting structures
- Global considerations: US, Europe and Asia

Shahin Gharakhanian MD, *Principal & Founder*, **SHAHIN GHARAKHANIAN MD CONSULTING LLC**

12:15 **Luncheon**

1:15 **Workshop Discussion with Attendees**
Challenges/Opportunities for the Alignment of Medical Affairs Within Different Organizations.
An interactive discussion with attendees

Panelists:

Shahin Gharakhanian MD, *Principal & Founder*, **SHAHIN GHARAKHANIAN MD CONSULTING LLC**

Purohit Prakash PhD, *Head of Scientific Affairs US/NA*, **IPSEN PHARMA**

Tyke White, BS, MBA, *Senior Director of Medical Alliances, Global Medical Affairs*, **VERTEX PHARMACEUTICALS**

2:15 **Building Medical or Scientific Affairs, Do You Know Where To Begin?**

Establishing a New Medical Affairs Group

- Understand its roles and responsibilities
- Define the needs of a Medical affairs team within the organization
- Have a Personal Plan and hold yourself accountable!
- Develop a cohesive Medical Affairs team: hire the right people
- Align Medical Affairs with company values
- Create value: hence the importance of feedback
- Ensure efficiency and internal cost effectiveness
- Ensure external cost effectiveness: agencies, consultants, vendor management

Tyke White, BS, MBA, *Senior Director of Medical Alliances, Global Medical Affairs*, **VERTEX PHARMACEUTICALS**

3:00 **Networking & Refreshment Break**

3:15 **Meet-the-Expert Session I**
Establishing a Compliant Medical Affairs Department

Paula D. Leca, *General Counsel*, **NEW YORK GENOME CENTER**

4:15 **Day One - Review Summary:**

- Why does your company need to have a Medical Affairs Department?
- What should Medical Affairs look like within your company?
- What role should it play?
- Looking ahead to Day 2....How do you do it?

5:00 **Day One Adjourns**

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DAY TWO

LAUNCHING A HIGH-VALUE MEDICAL/SCIENTIFIC AFFAIRS TEAM WEDNESDAY, JANUARY 23, 2013

9:00	People Power: We're Going to Build or Grow our Medical Affairs Department! So, Now What? <ul style="list-style-type: none"> Review of Day One (Why, What it looks like, Role). Overview of Day Two (Team, Systems, Standards, Medical Plans). 	12:00	Lunch
9:15	Phenotypes of Successful Medical Affairs Hires <ul style="list-style-type: none"> Defining roles and job descriptions HR interactions in the hiring process Medical Directors MSL Directors Medical Communications & Information Staffing "Specialized" capabilities: <ul style="list-style-type: none"> Health economics, Investigator-Initiated Studies/Phase IV Publications Other critical hires? Which internal process (team, HR interactions, checklist) is required to ensure successful hiring in Medical Affairs? On-boarding, an integral part of the hiring process. Barry Lubarsky MD, Director, Medical Affairs, VERTEX PHARMACEUTICALS	1:00	Your Medical Affairs Department Goes Global What is Needed and When? Thomas Gesell, Medical Affairs Leader, ENVISION TECHNOLOGY SOLUTIONS
10:15	Meet-the-Expert Session 2 Medical & Scientific Affairs Team Building: Processes & Activities: The Useful, The Useless and The Superfluous! <u>Panelists:</u> Barry Lubarsky MD, Director, Medical Affairs, VERTEX PHARMACEUTICALS Tyke White, BS, MBA, Senior Director of Medical Alliances, Global Medical Affairs VERTEX PHARMACEUTICALS	1:45	Key Operations within Medical Affairs Phase IV and Investigator-Initiated Studies <ul style="list-style-type: none"> Management of Investigator Initiated Studies Registries Lifecycle Management Phase IV Specific Coordinational Aspects Shahin Gharakhanian MD, Principal & Founder, SHAHIN GHARAKHANIAN MD CONSULTING LLC
10:45	Networking & Refreshment Break	2:15	Networking & Refreshment Break
11:15	Different Information Systems for Medical / Scientific Affairs Groups? Information Systems: What is Needed and When? <ul style="list-style-type: none"> Clinical Studies I Systems KOL Management <ul style="list-style-type: none"> Commercial systems and the potential for conflict/overlapGrant/IIS management MSL Information System Product & disease area-related Information databases Publication Planning Thomas Gesell, Medical Affairs Leader, ENVISION TECHNOLOGY SOLUTIONS	2:30	Review of Days 1 and 2 Medical Affairs Metrics...The Holy Grail? <ul style="list-style-type: none"> The need to establish accepted metrics for Medical Affairs Challenges and opportunities What are we trying to measure? Communicating medical metrics Tyke White, BS, MBA, Senior Director of Medical Alliances, Global Medical Affairs VERTEX PHARMACEUTICALS
		3:15	Medical Affairs: Tying It All Together - Medical Affairs As A Living Organization <ul style="list-style-type: none"> Implement, Embed and Reinforce in Cycles. The ultimate goal is to improve patient care Shahin Gharakhanian MD, Principal & Founder, SHAHIN GHARAKHANIAN MD CONSULTING LLC Tyke White, BS, MBA, Senior Director of Medical Alliances, Global Medical Affairs VERTEX PHARMACEUTICALS
		3:30	Concluding Remarks & Seminar Adjourns

COURSE LEADER

Shahin Gharakhanian, MD, DPH

Shahin Gharakhanian (SG) MD, DTM&H, DPH, has expertise in clinical development and medical affairs, and more broadly in pharmaceutical medicine, leadership & senior management, blending a record of achievements in the US & EU. Most recently, he was Vice-President (and founder) of the Medical Affairs Department within the Medicines Development Group/Global Research & Development of Vertex Pharmaceuticals Inc., Cambridge MA, USA. SG started working in the pharmaceutical industry in 1991. To date in this industry, he has held positions ranging from the General Manager of a full-service CRO to Program Executive leading product development, regulatory approval and launch. He has thus handled projects for 12 different companies, ten different brands and four drug launches, in different therapeutic areas and geographic regions [Asia, USA, EU]. SG has authored/co-authored ~150 abstracts, chapters in books, peer-reviewed publications, reports & training courses. He is a member of various societies, including the executive board of the Association of Medical Affairs Professionals (AMAP). He has now set up Shahin Gharakhanian MD Consulting LLC at the Cambridge Innovation Center (Cambridge MA), and has ongoing collaborations with both small biotechnology start-ups and major pharmaceutical companies. The LLC focuses on the clinical development of novel anti-infective agents, medical affairs and professional education.

GUEST EXPERT

Tyke White, BS, MBA, Senior Director of Medical Alliances, Global Medical Affairs, VERTEX PHARMACEUTICALS

Tyke White (TW) is currently Director of Medical Alliances, Global Medical Affairs, Medicines Development Group/Global Research & Development at Vertex Pharmaceuticals Inc., Cambridge MA, USA. TW has a very comprehensive track record in medical affairs including (but not limited to) directing medical science liaisons in the US & EU, medical education, program management, directing medical affairs operations, financial & HR planning, process management & implementation and medical affairs compliance. He was one of the architects of the Medical Affairs Department within Vertex Pharmaceuticals Inc. Prior to that, he had worked for over 7 years within the Medical Science Liaison Group at Abbott Laboratories in the United States. During his pharmaceutical career, TW has notably set up MSL groups both nationally and internationally, carried out strategic planning and, especially, has been a member of the launch teams for three new drugs in different therapeutic areas. TW holds a BS from the University of Pittsburgh and an MBA from George Mason University – School of Management.

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and discussion,”***

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