

## 제20차 바이오의약품 포럼

- 세계 진출을 위한 바이오의약품의 임상 및 마케팅 허들 대응 전략-

- ◆ 일시 : 2016년 3월 31일(목) 10:00~15:00
- ◆ 장소 : 서울 COEX 컨퍼런스룸 300호(3층)
- ◆ 주최 : 한국제약협회, 한국바이오협회, 코리아헬스포럼, 한국보건산업진흥원
- ◆ 프로그램

시간	내용	발표자
10:00~10:30	등록	
좌장: 이동호 교수, 울산대학교 의과대학		
10:30~11:00	유럽 진출을 위한 인허가 전략 - 바이오시밀러 사례	삼성바이오에피스 RA팀 박형기 부장
11:00~11:30	세포유전자치료제의 미국 FDA 임상시험 승인을 위한 체크포인트	Dr. Andra Millar Director, Cell & Gene Therapies, Senior Consultant Biologics Consulting
11:30~12:00	해외 임상시험 진행 시 위험 관리 방안	Travis McIntosh Life Science Specialist, Asia Pacific Zone Chubb Group of Insurance Company
12:00~13:00	중식	
좌장: 최진우 교수, 원광대학교 의과대학		
13:00~13:30	성공적인 미국 FDA 승인을 위한 의약품 포지셔닝 전략	Dr. Steven M. Walker Chief Business Officer(CBO) Biologics Consulting
13:30~14:00	글로벌 의약품 유통 관리 전략 및 최신 동향 (PIC/S, GDP(Good Distribution Practice), EU FMD Risk Management)	Dr. Ruediger Lomb Vice President, Global Quality & Technical Compliance, World Courier Management
14:00~14:30	세포치료제의 국내 임상시험 수행 시 고려사항	식품의약품안전평가원 세포유전자치료제과 정지원 과장
14:30~15:00	질의응답 및 폐회	

# The 20th Biopharmaceutical Forum

## - Strategic Planning to Overcome the Hurdles of Global Biologics Development -

- ◆ Date : March 31(Thur), 2016, 10:00~15:00
- ◆ Venue : COEX Conference Room.300, Seoul, Korea
- ◆ Host : KPMA, KoreaBio, Korea Health Forum, KHIDI
- ◆ Program

Time	Title	Speaker
10:00~10:30	Registration	
Session Chair Dr. Dong Ho Lee, Professor, Asan Medical Center		
10:30~11:00	Regulatory Strategy for EU - Biosimilars	Hyunki Park Director Samsung Bioepis
11:00~11:30	Check Point for US FDA Clinical Trial Approval of Gene & Cell Therapy	Dr. Andra Millar Director, Cell & Gene Therapies, Senior Consultant Biologics Consulting
11:30~12:00	Best Practice Risk Management for Global Clinical Trials (Insurance Agreement)	Travis McIntosh Life Science Specialist, Asia Pacific Zone Chubb Group of Insurance Company
12:00~13:00	Lunch Break	
Session Chair Dr. Jin Woo Choi, Associate Professor, Wonkwang University		
13:00~13:30	Positioning Your Product for Efficient Success with the US FDA	Dr. Steven M. Walker Chief Business Officer(CBO) Biologics Consulting
13:30~14:00	Securing the Global Pharmaceutical Supply Chain (PIC/S, GDP(Good Distribution Practice), EU FMD Risk Management)	Dr. Ruediger Lomb Vice President, Global Quality & Technical Compliance, World Courier Management
14:00~14:30	Points to Consider for Clinical Trials of Cell Therapy Products	Dr. Jee Won Joung Director, Cell & Gene Therapy Products Division NIFDS, MFDS
14:30~15:00	Closing	

## Speaker Information



### **Andra E. Miller, PhD, Senior Consultant, BCG(Biologics Consulting Group, Inc.)**

Dr. Andra Miller joined Biologics Consulting as the Director of Cellular and Gene Therapies in July 2000. Dr. Miller is a molecular biologist with 9 years of experience with the U.S. Food and Drug Administration (FDA).

As Gene Therapy Group Leader and Expert Microbiologist in the FDA's Division of Cellular and Gene Therapies, CBER, Dr. Miller has been very influential in the development of policy in the cell and gene therapy areas. She had a major role in writing the 1998 Guidance for Industry for Somatic Cell and Gene Therapies and in developing new policy on testing for replication competent retrovirus. She also served as CBER lead on development of proposed regulations on disclosure of gene therapy and xenotransplantation products. Additionally, Dr. Miller's experience with the FDA includes serving as technical contact for recent inspectional activities at gene therapy investigational sites.

Dr. Miller has actively participated in national and international meetings in the field of gene therapy where she frequently represented the FDA as an invited speaker. She has planned and moderated regulatory and scientific sessions at the FDA Gene Therapy Conferences, most recently at the American Society of Gene Therapy annual meeting. Her earlier experience included research into control of gene expression during development using transgenic mice and *Xenopus* models at NIH and FDA.

For the past several years Dr. Miller has served as the FDA Alternate Representative to the Recombinant DNA Advisory Committee (RAC) and CBER Liaison to the Office of Biotechnology Activities (OBA) at the NIH. In this capacity, she coordinated activities between the two agencies, was responsible for discussion of FDA policy issues at RAC meetings and performed analysis of adverse event reporting to FDA and the RAC. Through these activities, Dr. Miller has acquired in-depth expertise in the RAC process and requirements. In addition, she has also participated in activities with the National Gene Vector Labs and is a member of the USP Advisory Panel on Gene and Cell Therapies, which recently drafted a general informational chapter, published in the Pharmacopeial Forum, Previews.

Dr. Miller's recognized expertise in the regulation of cell and gene therapeutic products, her extensive experience, active participation in the gene therapy community and her acknowledged understanding of the biologics development process significantly enhances the expertise and service provided by Biologics Consulting.

### **Education**

Ph.D. Genetics. George Washington University, Washington, D.C. (1991)

Dissertation: A transgenic mouse model to study immunoglobulin gene enhancer and promoter functional regulation.

B.A. Biology. Manhattanville College, Purchase, NY (1980)



**Dr. Steven M. Walker, Chief Business Officer(CBO), BCG(Biologics Consulting Group,Inc.)**

Steven M. Walker is the Chief Business Officer (CBO) at Biologics Consulting. Steven has over 20 years of biopharmaceutical business and life science experience, with a focus in immunology, respiratory, dermatology, vaccine, cardiovascular disease and neuroscience.

Prior to joining Biologics Consulting, he worked at MedImmune, specialty care division of AstraZeneca and served in multiple roles including Director of New Product Planning for Respiratory, Inflammation and Autoimmunity (RIA), as well as Director of Cross Franchise Initiatives for the Infectious Disease division (Synagis® - Palivizumab and FluMist® - LAIV) and Marketing Director for FluMist®. Steven also spent several years at Genentech, Inc., in roles of increasing commercial responsibility - Senior Respiratory Marketer, Division Manager in Dermatology and Regional Sales Director in Respiratory, with responsibility for products such as Xolair® - Omalizumab and Raptiva®- Efalizumab. He has also worked in other business functions ranging from Corporate Strategy, Claritin® - Loratadine Marketing, Sales and Sales Management with the Schering-Plough, corporation. He holds a B.S. in Neuroscience from the University of Pittsburgh, M.B.A. from Joseph M. Katz Graduate School of Business at University of Pittsburgh, and a M.H.A. from the Graduate School of Public Health at University of Pittsburgh.



**Dr. Rüdiger Lomb, Global Quality & Technical Compliance for the World Courier Group of Companies**

Dr. Rüdiger Lomb is Vice President, Global Quality & Technical Compliance for the World Courier Group of Companies as well as for Integrated Commercialization Solutions (ICS).

In this role, Dr. Lomb oversees the Quality program for World Courier's company-owned network of 13 investigational drug storage facilities and more than 140 offices in 50-plus countries as well as for ICS facilities in Frisco, TX, Louisville, KY and Reno, NV.

He is responsible for ensuring facility compliance with all current and future GxP standards such as the relevant FDA Guidelines, the most recent EU Good Distribution Practices Guidelines and other relevant Quality standards.

Dr. Lomb is a licensed pharmacist and holds a Ph.D. in pharmaceutical bio-chemistry. Together World Courier and ICS form the Global Specialty Logistics (GSL) division of AmerisourceBergen Specialty Group (ABSG).

**Additional notes on Ruediger's background:**

- Started 1996 in pharma, was in QA since 1997, then moved into pharma logistics in 2004 and in current WC role since 2008.
- Pioneered the Global Quality Program and implementation in WC



**Travis McIntosh, Life Science Specialist, Asia Pacific Zone,  
Chubb Group of Insurance Company**

Travis is Chubb's Life Science Specialist for the Asia Pacific region. In his current role Travis is responsible for product development, technical support and training and delivery of underwriting strategy for Chubb's Asia Pacific Life Sciences portfolio.

Travis has over 23 years of insurance industry experience in both broking and underwriting roles. He joined Chubb in 2001 as a Senior Casualty Underwriter and has since held various management positions. For the last 10 years, Travis has specialised in providing casualty insurance solutions to Life Science companies and is widely recognised as being one of the leading specialists in his field. Travis holds a Bachelor of Commerce in Insurance, Management and Business Information Technology and is a Fellow at the Australian and New Zealand Insurance Institute (ANZIIF) and Certified Insurance Professional (CIP).