# 모시는 글

한국 머크 생명과학 사업부 Process Solutions에서 개최하는 Formulation Symposium 2017에 초대합니다.

국내 제약회사 연구소 및 생산 현장에서 제제 개발, 품질 보증 및 관리, 허가, 기획 및 구매 등 실무에 정진하고 계시는 실무자 분들을 대상으로 제제 기술과 경험을 공유하고 교류할 수 있는 기회가 될 것입니다. 이번 행사는 '한중일 아시아 투어 심포지엄' 행사로 신기술 및 트렌드 파악 및 동종 업계 종사자 분들이 한자리에 모여 커뮤니케이션 할 수 있는 장이 될 것 입니다.

귀한 시간 내주시어 자리를 빛내 주시면 감사 하겠습니다.

주 제: Global Trends in Formulation & Regulations

일 시: 2017년 9월 15일 10:00-16:00

장 소: JW 매리어트 서울 3층

# 오시는 길


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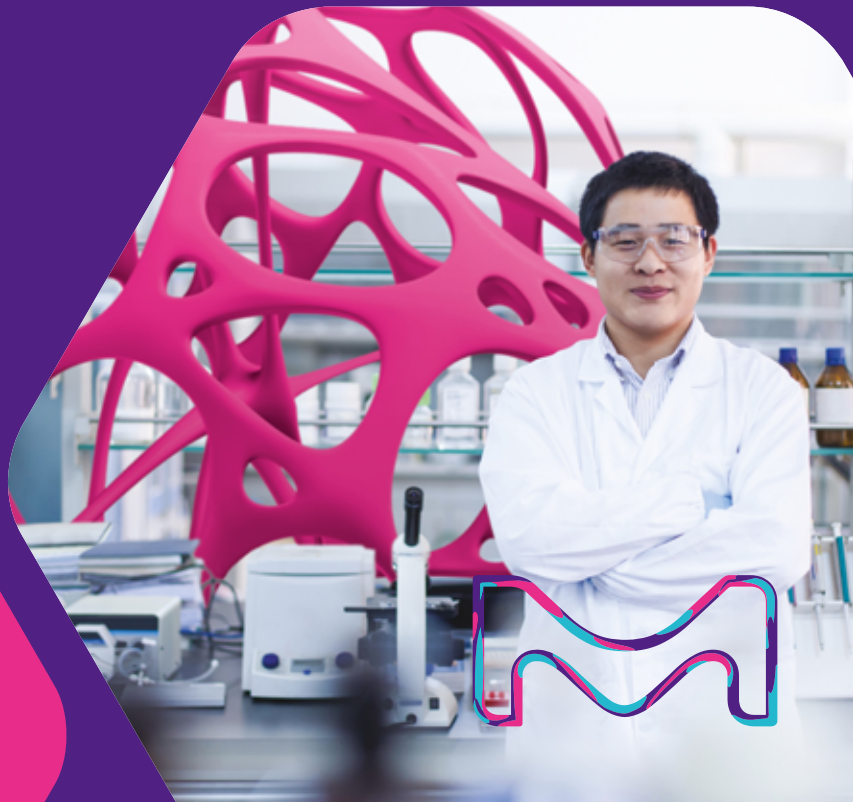
# formulation symposium 2017

Global Trends in Formulation & Regulations



# 연사 소개

**Dr. Finn Bauer**
Director and Global Head
Solid Formulations R&D,
Merck KGaA, Germany

Dr. Finn Bauer is Director and Global Head for Solid Formulations R&D at Merck in Darmstadt, Germany, recently launching two PVA-based excipients for sustained release matrix systems and solubility enhancement through hot melt extrusion.

With broad experience in managing product and application development projects, he has guided many programs in his more than 10-year career within Merck, covering positions from Quality Control and Project Management to R&D and Site Manager in our US subsidiary.

He is a biochemist by education and holds a Doctoral degree from the University of Bayreuth, Germany. Most recently he received his Master of Business Administration from Ashridge Business School, Berkhamsted, UK.

**Dr. Yi Feng Lee**
Technical Product Manager
Excipients for Liquid Dosage,
Merck KGaA, Germany

Dr. Yi Feng Lee joined Merck from Steinbeis GmbH & Co.KG, Mannheim, Germany where he was working in research and development for downstream processing, protein purification and protein biochemistry

He holds a Ph.D. in Biotechnology from the Medical Faculty Mannheim of Ruprecht-Karls-University Heidelberg, Germany. His PhD project was sponsored by Merck from 2011 to 2014. He researched on the improvement of monoclonal antibody drugs by selective removal of immunogenic contaminants like multimers and host cell proteins supported by the R&D department for chromatography.

**Dr. Torsten Schadendorf**
Associate Director
Marketing EMPROVE®,
Merck KGaA, Germany

Dr. Torsten Schadendorf is Associate Director of Marketing EMPROVE®. He has been working for Merck KGaA for 9 years in various marketing fuctions in the area of raw and starting materials for (bio-) pharma application.

Since the beginning of this year he is responsible for the EMPROVE® program for Merck's excipients and process chemicals for pharmaceutical production, supporting drug manufacturer's risk assessments, management and mitigation. He holds a PhD in Organic chemistry obtained from TU Berlin.

**Stella Sun**
Senior Manager
Regulatory Management,
Life Science, Merck Ltd Korea

Stella Sun is Senior Manager of Regulatory Management of Merck Life Science Korea. She supports businesses of pharmaceutical excipients, APIs, food additives, biopharm process, medical devices/IVDs, equipment and animal derived materials.

She previously worked in Johnson and Johnson Medical and Glaxo Smith Kline, in charge of regulatory affairs and quality assurance.

She received master's degree in Social Administration Pharmacy and received bachelor's degree in Pharmacy.

# 세미나 일정

| Time | Topic | Speaker |
|---|---|---|
| 10:00-10:15 | 개회사<br>Introduction | Manjeri S. Mahadevan |
| 10:15-11:00 | 독일 머크 신규 개발 원료의약품 및 최근 연구개발 업무 소개<br>Merck Actives & Formulation R&D - Solid and Liquid Applications: Mission, Capabilities & New Products 2017 | Dr. Finn Bauer |
| 11:00-11:30 | 유럽 및 북미의 원료의약품질 규격 경향 소개<br>EU/US API & Excipients New Regulatory Trends | Stella Sun |
| 11:30-12:00 | 유럽 의약품 부형제 위험성 평가 최신 가이드라인의 이해<br>EU Risk Assessment for Excipients | Stella Sun |
| 12:00-13:00 | 점심<br>Lunch | |
| 13:00-13:30 | PVA를 이용한 최적화된 서방형 내용고형제 기술 소개<br>Solid Applications: Sustained Released Tablets Using PVA-based DC Formulations | Dr. Finn Bauer |
| 13:30-14:00 | 생물학적 제제용 의약품 부형제 소개<br>Liquid Applications: Excipients for Biomolecule Formulations | Dr. Yi Feng Lee |
| 14:00-14:30 | 쉬는시간<br>Break | |
| 14:30-15:00 | 의약품 금속불순물 가이드라인 및 의약품 부형제 인증규격의 이해<br>ICH Q3D and EXCiPACT | Dr. Torsten Schadendorf |
| 15:00-15:40 | 머크 엠프루브 품질 평가 시스템 소개<br>EMPROVE® | Dr. Torsten Schadendorf |
| 15:40-16:00 | 질의응답<br>Panel Discussion | Chair: Tae-Kyun Kim |
| 16:00-16:10 | 폐회사<br>Closing | Tae-Kyun Kim |

# 참가 신청

참가 신청을 원하시면 소속, 성함, 부서 및 이메일 주소를 작성하시어 아래의 이메일 또는 QR코드 스캔을 통해 사전 등록 해주시기 바랍니다.

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