

바이오횰약품의 용기 및 포장 적합성 평가 교육

◆ 일 시 : 2017년 11월 14일(화), 09:30~17:30

◆ 장 소 : 한국제약바이오협회 4층 강당

◆ 주 최 : 한국제약바이오협회 바이오의약품위원회

◆ 개최목적

- 현행 GMP 규정과 규제당국에서 요구하는 바이오의약품 용기 및 포장 적합성 평가의 핵심 주제인 '용출물 및 침출물 시험(E&L Study)' 수행·관리 방안과 바이오의약품 생산 시 사용되는 일회용품에서 유래되는 용출물 및 침출물의 관리 방안을 교육하여 환자 안전 및 의약품 품질 유지를 제고하고자 함.

◆ 프로그램

시 간	내 용	발 표 자
09:00~09:30	등록	
09:30~10:20	바이오의약품 생산 시 일회용품 활용에 대한 최신 동향 및 규제 Current trends & regulatory requirements in single use bioprocessing	Minh Tran (Head of Single Use Sales Development-Asia Pacific, Merck)
10:20~11:00	일회용품 사용하는 생산공정 밸리데이션에서 용출물 및 침출물 시험의 중요성 Why Extractables & Leachable (E&L) testing is an important of single use validation?	
11:00 ~ 11:20	휴식	
11:20~12:30	바이오의약품 생산 시 일회용품의 용출물과 침출물에 대한 사례 E&L case studies	Minh Tran (Head of Single Use Sales Development-Asia Pacific, Merck)
12:30 ~ 13:30	중식	
13:30 ~ 14:10	용출물과 침출물의 개요 및 중요성 Introduction and Importance of E&L	Patty H. Kiang, PhD. (Kiang Consultant Services, LLC)
14:10~15:00	용출물과 침출물 관련 법규와 모범 사례 Regulations and Best Practices of E&L Assessment	
15:00 ~ 15:20	휴식	
15:20 ~ 17:00	결합제품의 용출물과 침출물 시험 E&L Studies of Combination Products	Patty H. Kiang, PhD. (Kiang Consultant Services, LLC)
17:00~17:30	질의응답 및 폐회	

※ 프로그램은 당일 사정에 따라 일부 변경될 수 있습니다.

※ 한·영 동시통역 제공됩니다.

◆ 강사소개

Minh Tran (Head of Single Use Sales Development - Asia Pacific Merck Life Science)

Minh Tran is the Head of Single Use Sales Development at Merck. He joined Millipore in 2009 after 17 years working in the biotechnology field with the last five with Amgen as Process Engineer Group Leader with extensive hands on experience in process scale-up and process transfers. Presently, he leads a dynamic team Single Use Specialists and provides technical consultation on single use manufacturing technologies to both internal teams and customers throughout Asia Pacific.

He worked closely with the top pharmaceutical, vaccine and CMO customers to provide disposable process and technology improvements through the use of Mobius single use products. He has helped numerous customers in the biotechnology, pharmaceutical, vaccine and animal health industries to implement new disposable technologies for upstream, downstream and final fill projects. He has also performed process review, designed full single use suites for cGMP upstream and downstream unit operations, including sterile filtration, sampling, storage, fluid transfer, fill finish and closed processing unit operations.

Minh has over 25 years of industry experience in the Biotechnology, which includes cGMP manufacturing, technology transfers, process development and scale-up before he joined Millipore. He graduated from University of Washington in Seattle, USA in 1991 with a Bachelor of Science, Microbiology and Cell Biology.

Patty H. Kiang, PhD. (Kiang Consultant Services, LLC)

Dr. Kiang specializes in pharmaceutical packaging and delivery devices for liquid and lyophilized products, prefilled syringe systems, and CMC support for combination products. Patty helps clients selecting or developing prefilled syringe and injection devices, identifying and managing fill/finish CMO vendors, and managing assessment of extractables and leachables for primary container closure systems and in-process components such as single-use containers.

Patty was Head of Device Development for Genentech and led the development of a new autopen injector for human growth hormone. Prior to joining Genentech, she held positions as Director, Drug Products for Schering Plough, and Director of Technology Development for West Pharmaceutical Services in Exton, PA, a developer and manufacturer of parental drug packaging components, where she collaborated with corporate partners in Japan and Germany in the development of various new products.

Patty is a member of the faculty of the PDA's Training and Research Institute, where she teaches courses on Prefilled Syringe & injection devices and Parenteral Packaging; she also served as committee or conference chair for USP Packaging Expert Committee, PDA Sterilization of Polymeric Materials Committee and PDA Global Prefilled Syringe & Injection Device Conference. She was president of the Chinese Bioscience Association in Northern CA – 2011, Dr. Kiang holds five patents in the field of polymeric surface coatings. She received a Ph.D. in Analytical Chemistry from Villanova University and holds an MBA from Pennsylvania State University.