

**K+F ÉS LABORATÓRIUMI MENEDZSMENT 2019**

Topics	Lecturer	Date
Biopharmaceutical R&D Quality by design (QbD) and process analytical technology (PAT) The GMP gradient	Könczöl Kálmán  Könczöl Kálmán	Október 8. 13:15-16:00
Biopharmaceuticals and biosimilarity – from analytical perspective Facility design and qualification	Lenkey Krisztián  Könczöl Kálmán	Október 15. 13:15-16:00
Process design and development Process characterization and control strategy Formulation challenges	Benkő Zsuzsa Sütő Zoltán Kollár Éva	Október 29. 12:15-15:00
Biopharmaceuticals & Biosimilars Analytical method development Analytical method validation and transfer Bioassay development Bioassay validation and transfer	Bogsch Erik Schäfer Tamás  Rábai Erzsébet	November 5. 12:15-15:00
Organizational structure and procedures Lean laboratory setup and management Comparability and QTPP Regulatory affairs Project management – a case study (Terrosa)	Szabados Hajnalka (betegség miatt elmaradt) Kovács Piroska Megyeri Márton Siminszky Balázs Fogassy Katalin	November 19. 12:15-15:00