Final sessions and session descriptions (ECI Single-Use Technology Conference)

Session 1: Polymers in new biopharmaceutical applications

Magali Barbaroux (Sartorius)
Sheryl Kane (Amgen)

This session will focus on new developments in polymer products that are used or intended to be used in biomanufacturing. These may include, but are not limited to, 3D printing, overmolded silicone etc. Focus will be on how different single-use components are manufactured, what is involved and what are the important parameters and properties to ensure a good product. Case studies are invited that address one or more of the following questions: Are there applications that current technology can't meet, but could be met with a Single Use material with different properties? Can polymers and films be optimally designed for specific applications? Can lessons/challenges from other industries (e.g. Single-use pre-filled syringes, IV bags) be leveraged for bioprocessing? Case studies where a company applied lessons from one area or industry to another are encouraged.

Session 2: Interaction of polymers with bioprocess fluids and bioproducts (including Extractables and Leachables and impact of particulates)

Susan Burke (GE Healthcare)
Xueyuan Wang (Bayer)

This session will focus on new findings related to the interaction of extractables/leachables with cells or proteins. The session will also focus on understanding the chemical basis of these interactions and potential preventive measures. In addition, studies on the influence of contact time on proteins or cells are invited. What can be learnt from other areas on this specific topic e.g. fill finish and formulation? Can extractables be prevented or strategies devised to minimize their release? The session will focus on science-based procedures and analysis of extractables/leachables and how newly developed procedures have impacted bioprocessing.

Session 3: Sensors and their integration with single-use technology

Gernot John (Presens)
Prashant Tathireddy (Applied Biosensors)

This session will focus on the development of sensors and challenges related to integration of sensors with single-use technology. Can we adapt or transform traditional sensor technology into a reliable and robust single-use sensor? Can sensor technology catch up with single-use technology implementation? The session will also focus on novel sensors for bioprocess or biomedical applications.

Session 4: Single-Use advantages in continuous and connected processing

Ruben Carbonell (NCSU)
Ekta Mahajan (Genentech)

This session will focus on how single-use technology has enabled or accelerated the development of end-to-end continuous processing for biopharmaceuticals production. Key question to be debated in this session include: Has single-use technology facilitated the integration of different process steps? What are the challenges associated with the development of perfusion processes and maintenance of high cell densities using single-use bioreactors? What are the challenges associated with implementing one or more connected steps or fully continuous downstream processes when processing high titers from perfusion/batch processes? What are the limitations of single-use equipment including analytical sensors in this space? Studies addressing product quality concerns originating from SUS (e.g., bioburden, endotoxin, particulates and E/L) as well as new single-use solutions for robust and scalable continuous processing are encouraged.

Session 5: Single-use adoption for cell and gene therapy applications

Margarida Serra (iBET)
Tiffany Hood (MilliporeSigma)

Single-use systems are considered a promising technology for manufacturing viral gene therapies and modified cell therapies because they can facilitate rapid turnaround times between campaigns. This session will focus on the advancements made in this area and on examples where closed automated solutions have enabled commercial manufacture, ensured consistent quality and/or met commercial demand. At what stage in process development should we consider adoption of single-use equipment? Are there examples of novel technologies able to harvest, concentrate, wash while maintaining cell viability and quality. Case studies demonstrating the impact of adoption of single-use technology on time-to-patient, reproducibility, reliability and scalability are particularly encouraged.

Session 6: Single-Use performance

Peter Neubauer (TU Berlin)
Regine Eibl (ZHAW)

This session will focus on the generic challenges faced when operating single-use equipment and the proposed solutions. Questions we aim to address include: What are the current approaches to prevent leaks and improve product robustness? What are the current industry standards, what type of tests are conducted and what is the test sensitivity, to ensure the integrity of bags and assemblies? Can integrity requirements be met at point of use (POU) or are we introducing more risk? Case studies about supplier quality release method development as well as end user POU acceptance best practice are beneficial. Studies of the correlation between chemical and physical properties of the polymer (e.g. film) and integrity (e.g. leak), impact of film blowing for integrity testing followed by gamma irradiation on physical/mechanical characteristics, as well as E/L, are especially welcome.