Summary of the 2019 CPAC Summer Institute

The theme of the 2019 CPAC Summer Institute was Next Generation Processing Approaches to Enable Maximum Efficiency in the Production of Pharmaceuticals, Specialty Chemicals, bulk chemical, petrochemicals and biomaterials. The theme was designed to build on the growing awareness that developed at the 2019 CPAC Rome meeting which was the rapidly building technical challenges that will be required to be solved to move to a circular economy.

The concept of a circular economy is rapidly increasing in significance and will have a much wider impact due to the growing knowledge that the world needs to do a better job of conserving all forms of finite raw materials. To build more understanding of the concerns and relate them to the technical challenges involved, there was a strong focus on defining the Circular Economy in the plenary talk of this meeting. It defined the looming shortage of finite resources and how that is tied to the need for new business models to end the linear economy by much more effectively using and reusing existing resources.

A key part of the need is to move to a circular bioeconomy which will reduce the use of single use plastics as well as reducing the burning of finite fossil fuels. Achieving the switch to new materials sources and the recycling of materials will require significant technology advances. The program was structured to present a range of technology topics and discuss how they fit with achieving a circular economy. Ray Chrisman of MK Optimization and Control – and a Dow Chemical retiree – presented the plenary talk entitled ‘The Circular Economy; What is it and Will it Happen.

Most of the presentations at this CPAC Summer Institute were focused around solving present problems and / or advancing existing areas of technology – and only sort of related to the topic of a circular economy. However, the presentations set the stage for subsequent discussion of how these areas could evolve into contributions to the theme. The presentations are divided according to an arbitrary
assignment to the various categories of: Advances in PAT, Assisting Continuous Manufacturing, Process Intensification, and Solution Providers.

**Advances in PAT**
As was expected, there were many talks in this category due to the academic projects at CPAC and instrument vendors with improved equipment. Recent advances in PAT are for the real time characterization of raw materials, as well as the analysis of complex biomass streams for process understanding. This data can be used for rapid process development and for feed forward and feedback control to enable high quality, cost effective processing.

**Wireless Sensor Platforms**
Chris Rudell, UW Electrical Engineering

**Battery Free Sensing and Communication**
Zerina Kapetanovic, Josh Smith, UW Electrical Engineering and Computer Sciences

**Advances in the Use of PAT for Developments in Process Control**
Brian Marquardt, UW, APL, CPAC, and MarqMetrix

**Expansion of PAT Tools with the Emphasis on the Integration of the Associated Technologies into an Integrated Informatics Communication, Analysis, and Control Solution.**
Ernie Hillier, Waters

**Advances in Analytical Sensing**
Richard Becker, Blaze Metrics

**New Developments in Benchtop NMR for Reaction Monitoring, Material Screening and Mixture Analysis**
Hector Robert, Magritek Inc

**How Low Can You Go?: Improving Limits of Detection for Raman Spectroscopy**
Bradford Behr, Tornado Spectral Systems

**Recent Advances in Software Development and Application of Two-Dimensional Gas Chromatography**
Sarah E. Prebihalo, Kelsey L. Berrier and Robert E. Synovec, UW Chemistry

**Improvements in Biopharma PAT with Sequential Injection**
Dan Hasle, FIAlab Instruments, Inc

**Ammonia Sensing with Single-Walled Carbon Nanotubes**
Alex Mamishev. SEAL Lab, UW Electrical Engineering
Industry Case Study SIFT-MS, A Discontinuous Innovation to Replace Finished Product Release for Odor by Panelist
Brian Goodlander, Procter and Gamble

Implementing Gas Chromatography for Real Time Process Analysis
Timothy J. Trinklein, Paige E. Sudol, Derrick V. Gough and Robert E. Synovec, UW Chemistry

Nuclear Magnetic Resonance for Food Science
Julia Kerr, Matt Augustine, Chemistry, U California Davis

Assisting Continuous Manufacturing
Next generation continuous manufacturing concepts for end to end bioprocessing as well as fermentation; including the process analytical technology (PAT) required to characterize organism growth and product production as well as product separation and purification.

Process Analytical Technologies for Bioreactor Monitoring and Control
James Collett, Pacific Northwest National Laboratory (PNNL)

A Machine Learning Approach to Calibrate Generic Raman Models for Real-time Monitoring of Cell Culture Processes
Aditya Tulsyan, Amgen

An On-line Continuous Monitoring Strategy for API Flow Chemistry
John-David McElderry, Biogen

Continuous Fermentation for Protein Production: Sensor Designs and Needs
Clem Furlong, Tom Bukowski, and Scott Soelberg. Medical Genetics and Genome Sciences, UW Medicine

Process Intensification
Utilization of process intensification approaches, at all manufacturing scales, including the use of novel operating windows, maximizing catalyst efficiency, and optimizing heat and mass transfer for the cost-effective introduction of new material including biomaterials.

The Medicines for All Initiative
Roger Stringham, Virginia Commonwealth University

Supporting Biotechnology Processes using Mass Spectroscopy through FDA Research
David Powers, US FDA CDER
Peptide-mimetic Sequence-Defined Polymers based on a New Synthetic Architecture: Triazine-Based Polymers  
Jay Grate, Kai-For Mo, Michael Daily, Greg Schenter, and Surl-Hee Ahn Pacific Northwest National Laboratory (PNNL)

**Solution Providers**
These were presentations on approaches to handle data generated by PAT and to develop effective process control systems. Utilization of new approaches in data handling including the use of big data - for end to end understanding and value extraction from chemical and biomass processing was presented.

**What's Next? The Changing Role of Chemometrics and Instrumentation for Process Analytics**  
Brian Rohrback, Infometrix, Inc.

**Statistical Process Control and Multivariate Analysis**  
Michael F. Roberto, Northwest Analytics

**Real Time PAT Based Knowledge Management and Control in Continuous Processes**  
Martin Gadsby, Optimal Industrial Automation Ltd., UK

**CMaT Data Analytics: Enabling Robust, Scaleable, Low-Cost Manufacturing of High Quality Therapeutic Cells**  
Theresa Kotanchek, Evolved Analytics LLC

**The Impact of Chromatographic Alignment**  
Brian Rohrback, Infometrix Inc.

Leading up the final discussion, Ray Chrisman presented a talk on selected topics that were presented at the CPAC Rome workshop in March 23-25, 2019. These topics were selected based on their association with the general theme of the CPAC Summer Institute – how to understand and achieve a Circular Economy. The final afternoon discussion summarized the technical areas and melded the conclusions into a broader look at the future impact of Process Analytical Technology (PAT) for achieving Process Optimization, and more importantly – how is this helping to achieve a circular economy.

The three-day program ended at an off-site location in the nearby Cascade Mountains with a BBQ dinner. CPAC has requested permission from the presenters to distribute their presentations. If copies of the various presentations
are of interest, please contact Mel Koch or Nan Holmes for details as to whether they are available.

The upcoming CPAC Rome meeting **March 23-25, 2020** will feature presentations that will demonstrate the rapidly expanding technology base that is evolving to enable the move to a circular economy.

CPAC has an established track record in fostering academic / industrial / national government agencies interactions, which aims at bridging the gap between basic research and full-scale process / product development. The CPAC Summer Institute provides continuing education opportunities in the areas of advances in measurement science and data handling – linked to effective process control.

The CPAC Summer Institutes are held in an informal format, with technical presentations, and time allotted for open discussion and brainstorming on topics that arise from this interaction. The informal environment has created a successful format for bringing together chemists, biologists, measurement scientists, and process engineers from industry, government, and academic institutions drawn from both CPAC and non-CPAC members.