

Advantages and Implementation of a Recipe Based Environment in Pharma, from Development to Manufacturing



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Monday, March 30, 2015

Lecture: 4:00-5:00 p.m.

[Physics Astronomy Building \(PAA\)](#) A118

Reception at 3:30 p.m. PAA A118

Abstract

The advent of Quality by Design (QbD) and the ICH Q8-Q11 regulatory guidance changed the pharmaceutical process development and manufacturing paradigm away from empirical based univariate process descriptions towards mechanistic based designs with multivariate interaction understanding. Parallel to the evolution of QbD, the emergence of the S-88 standard allowed separation of process control and plant control and introduced the concept of plant agnostic general process recipes. Taken together, QbD and S-88 provide an environment where fully developed processes can be moved from plant to plant with no impact to quality, minimal recipe translation and little to no at scale characterization needed.

Today the use of fully plant agnostic general recipes is still limited to few process types due to the difficulty of describing the process and their parameters at a fundamental level. As a result, the industry still expends significant effort and money performing at scale process characterization and validation even for process transfers between relatively similar equipment.

At Janssen Supply Chain we are engaged in a phased implementation of S-88 in the manufacturing network to help standardize equipment procedures and speed up translation of process recipes from one plant to the next. In this context we are developing modeling based workstreams starting at the R&D labs that will help us define the fundamental process parameters where possible. This will allow us to expand the process types for which fundamental process parameters can be determined and allow us to perform equipment characterization studies to determine how to deliver these parameters.

This presentation will cover the concepts of S-88, how it is impacting our plants and its relation to QbD as well as provide an overview of our efforts in developing modeling based workstreams that allow standardization of fundamental process parameters and plant capabilities. The presentation will focus on learnings from already developed workstreams, areas under development and future areas where additional fundamental academic collaboration may be required.

Speaker Biography

Mauricio Futran is the VP of Advanced Technology in the Technical Operations group of Janssen Supply Chain at JnJ, focusing on manufacturing process understanding and reliability.

Before joining JnJ Futran was professor and chair of Chemical and Biochemical Engineering at Rutgers University, after working for 28 years in various positions in pharmaceutical product and process development at Merck and Co. and Bristol-Myers Squibb, where he was Vice President of Process R&D. His areas of expertise include all aspects of process development, technology transfer, validation, regulatory compliance, new product registration, external manufacturing and partnership development.

Dr. Futran is a member of the National Academy of Engineering, where he has been chair of its ChemE section, and has served on the Board of Chemical Sciences and Technology, and an NRC panel. As an AIChE member he has served on the awards committee. He has been a member and chair of the Princeton Chemical and Biological Engineering external board, and has been a member of the external boards for the University of Illinois at Urbana Champaign, Georgia Tech, and Rutgers. Dr. Futran has Chemical Engineering degrees from Rice University and Princeton University.