

Biopharmaceutical Consortium

Developing Next Generation Bioprocessing Technology

Next Generation Biopharmaceutical Process

- Continuous Process
- Perfusion Cell-Culture / SMB / Continuous
- Harvest

New Operation Paradigms

- PAT / QbD
- Contamination Handling
- Advanced sensing technology
- Batch Process Control

Platform Biopharmaceutical Infrastructure

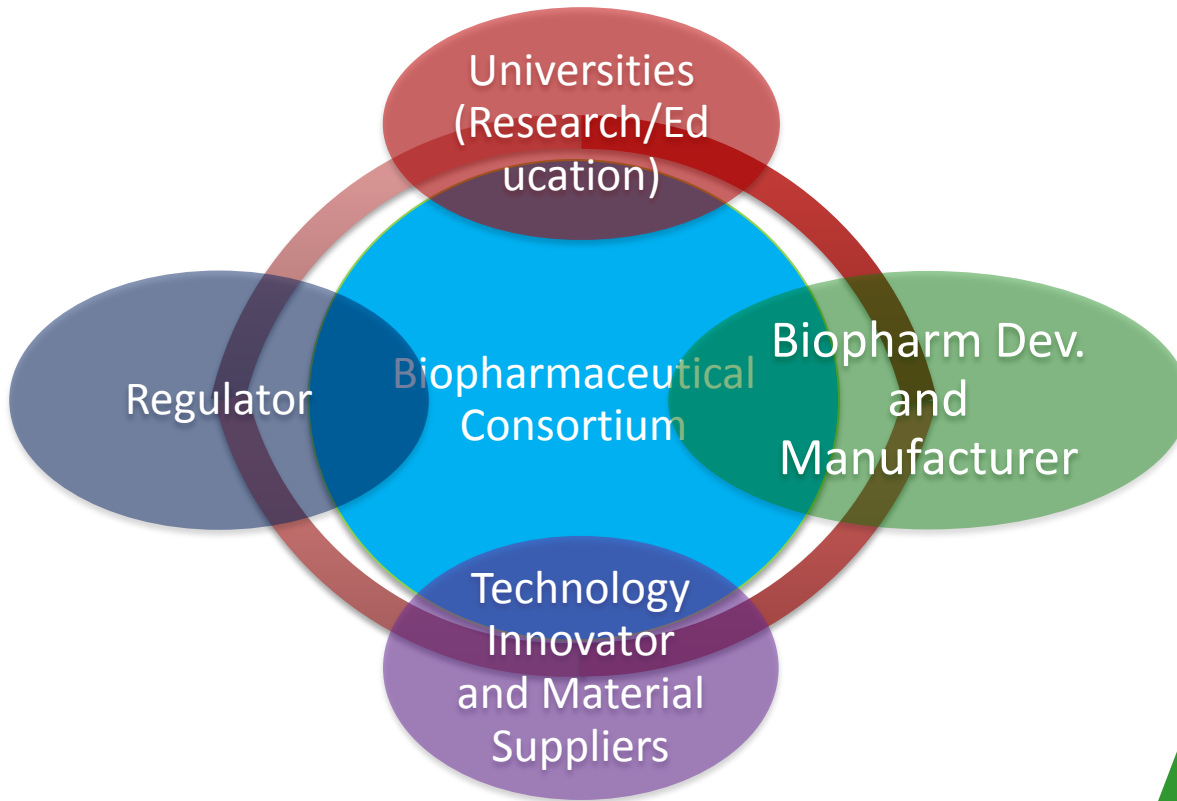
- Improvement and optimization
- Biosimilar development

Providing Scientific and Technology Paths for Biopharmaceutical Industry

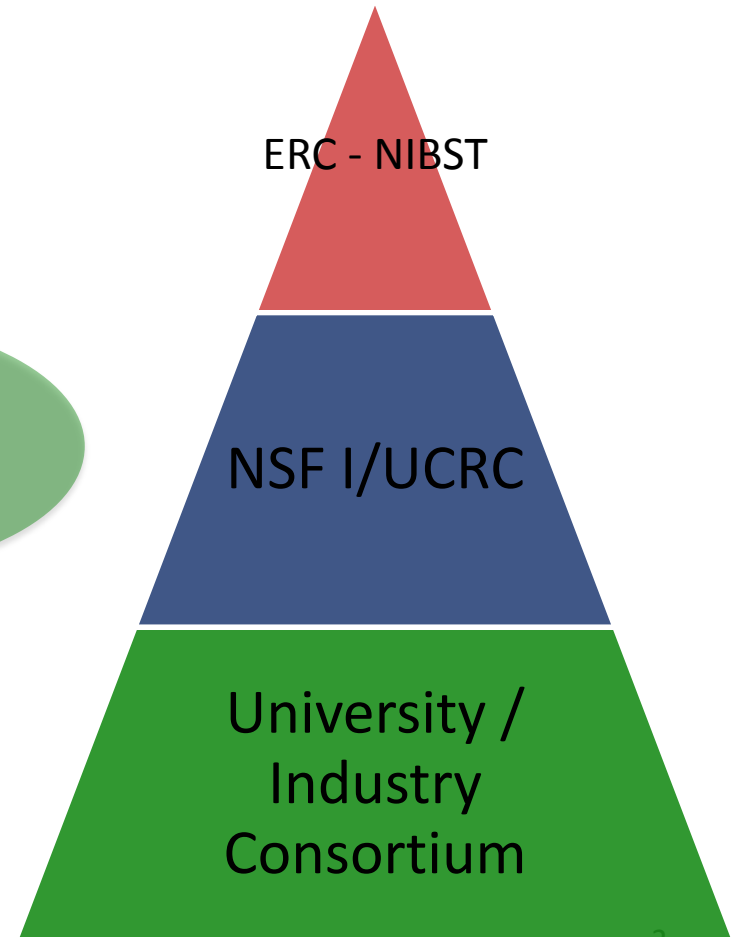
Biopharmaceutical Consortium

- Strategic Expansion of Mass BioManufacturing Center

Industry/Academic Partnership



Road Map



4th Biopharmaceutical Summit (2015)

May 18-22, 2015, Univ. of Massachusetts Lowell



**Special Issues in
Biopharmaceuticals : Workshop**
(May 2-22)

**Advanced Training in
Biopharmaceutical : Advanced
Training (May 18-29, 2015)**

Question: bpqc@uml.edu

2014 Engineering Process Analytics (Graduate Course)

Student's Term Paper Project

NBA Champion Prediction (2013-2014 season)

10.548 Engineering Process Analytics
Hangtian Shi
Chemical Engineering

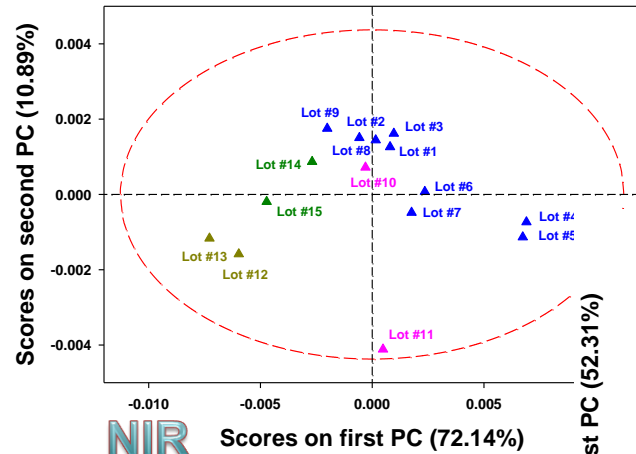


BiOPT - Biologics Optimizer

- Raw material characterization
 - Robust Cell-culture Diagnostics Tools
 - Robust Predictor of Product Quality Attributes
 - Downstream Performance Estimator
 - Design Space Tool
- Batch Controller

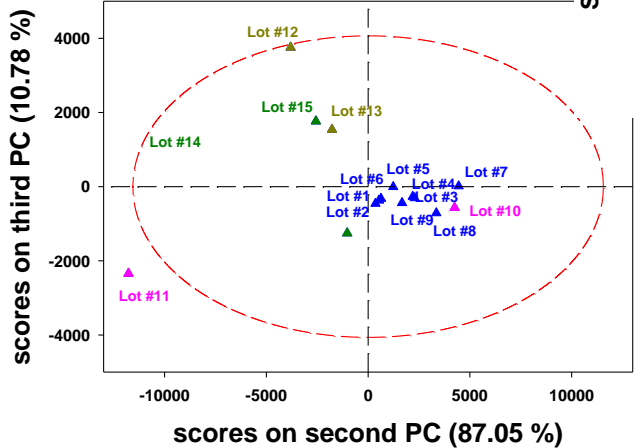
BiOPT

M1. Raw Material Assessment and Screening

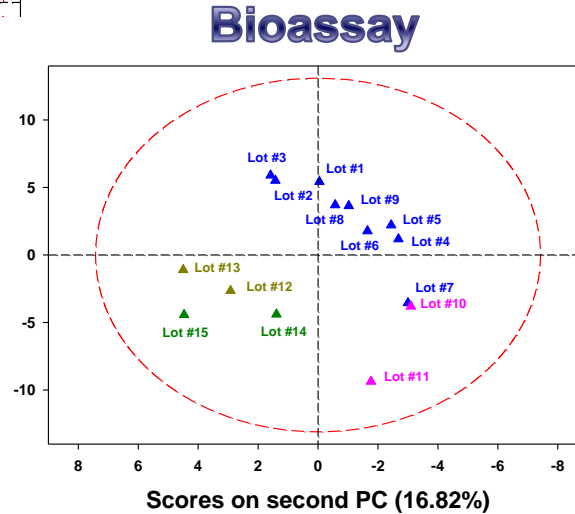


NIR Scores on first PC (72.14%)

fluorescence



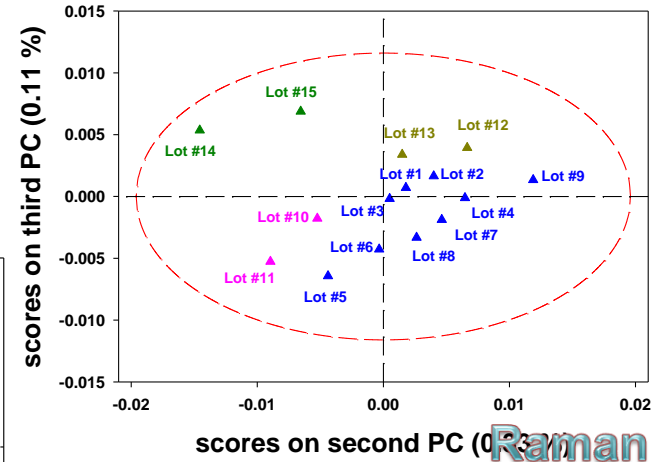
scores on second PC (87.05 %)



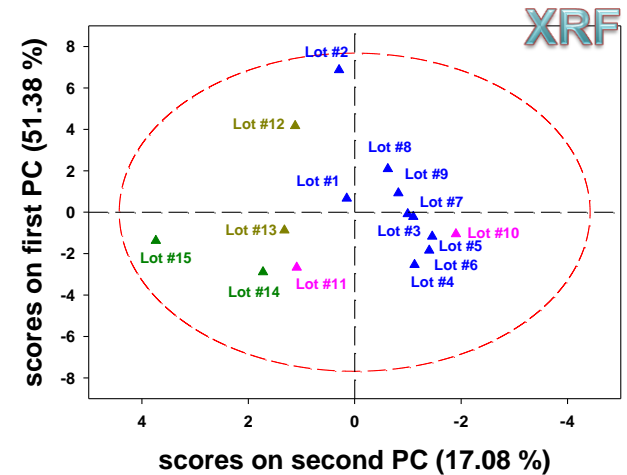
Bioassay

Scores on second PC (16.82%)

Different spectral measurements could identify lot-to-lot and vendor-to-vendor differences, but their information contents might be different with each other, providing complementary information about the composition of soy hydrolysates.



Raman

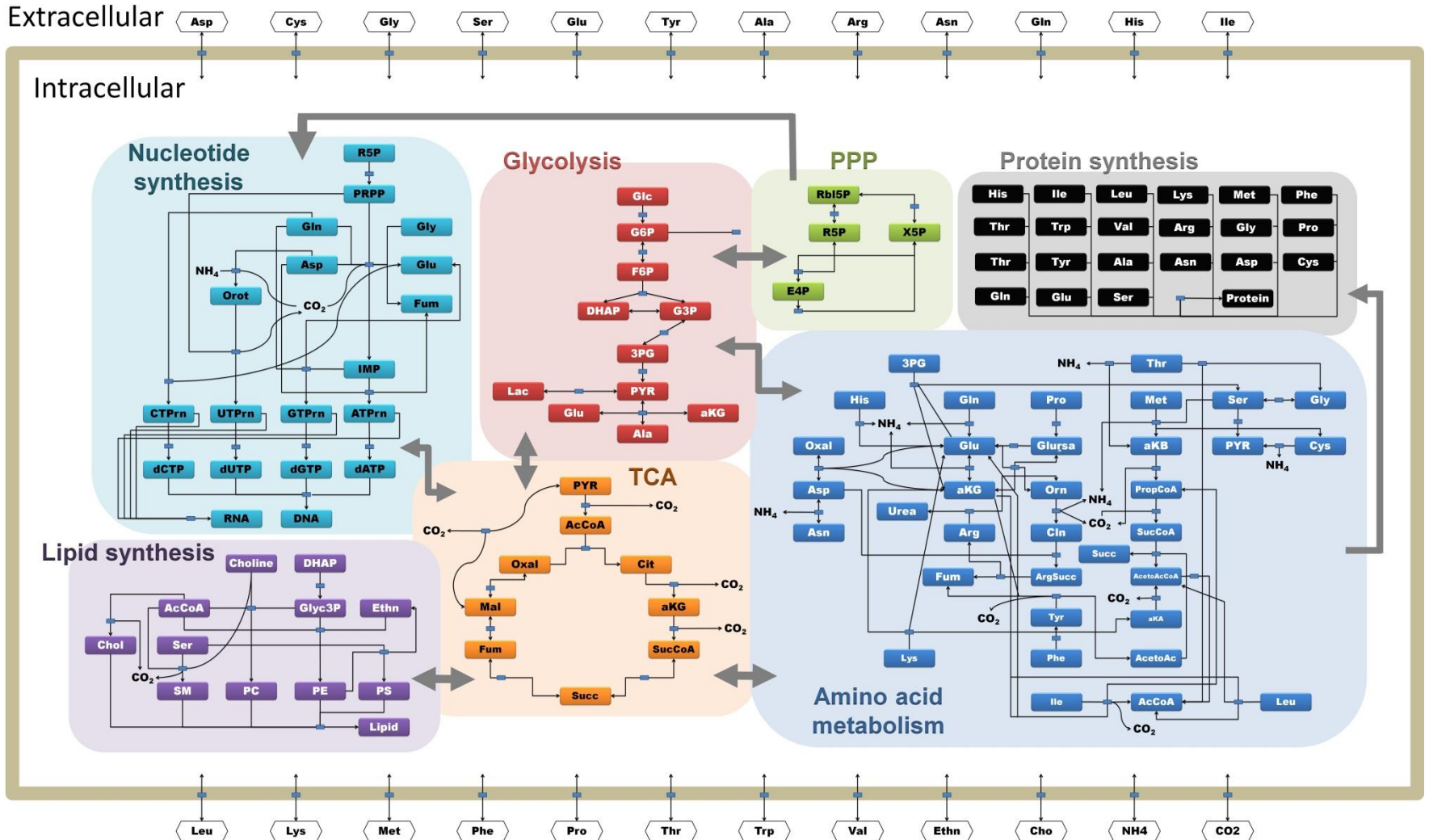


XRF

scores on second PC (17.08 %)

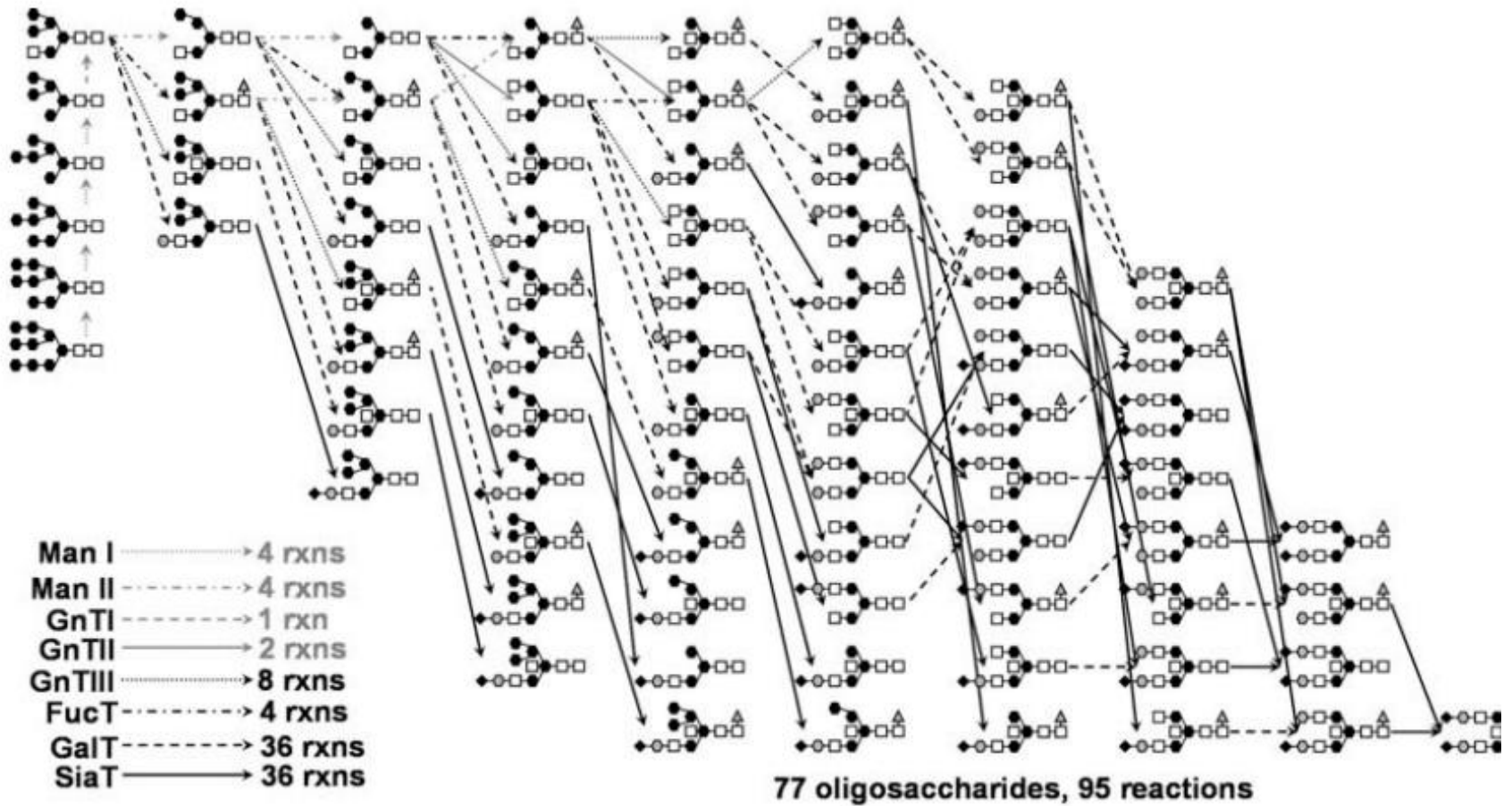
BiOPT

Module 2. Cell-Culture Diagnostics



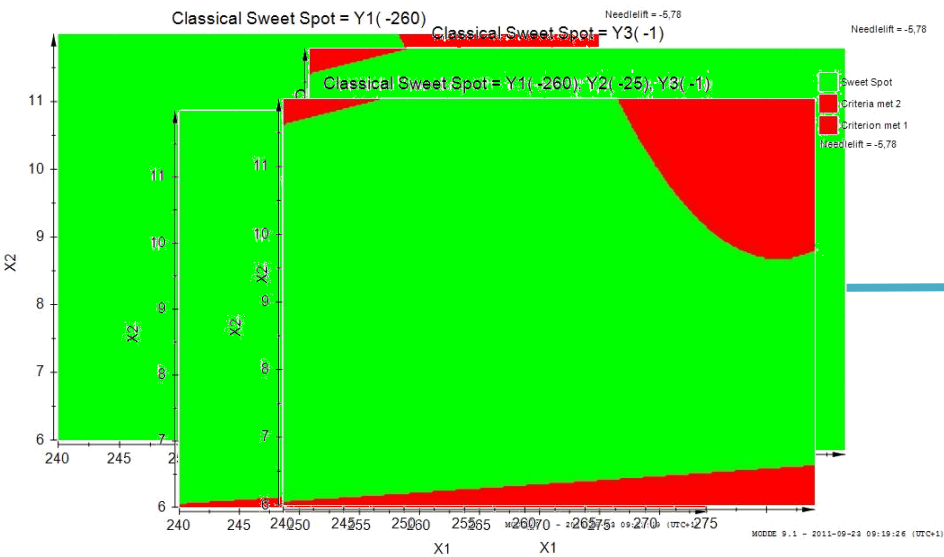
BiOPT

M3. Product Attribute Predictor

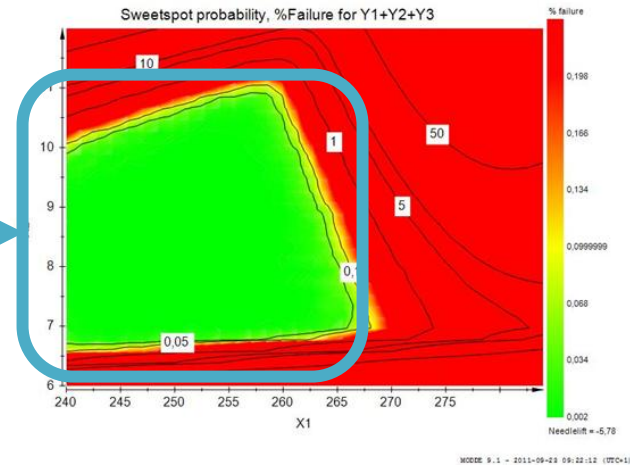


M5. Design Space Exploration

The probability estimation;
 Presents low risk region in a Sweet Spot type plot
 The probability acceptance region = a good estimation of Design Space



Probability Contour Plot



The low risk region is significantly smaller than the corresponding classical sweet spot region