Quality by Design has 3 core elements: 1. Risk Assessment; 2. Design Space, 3. Control Strategy.  This workshop focuses on equipping you with essential skills and experience to be an effective facilitator of QbD risk assessments. Through QbD case studies, best practices and the right tools, you will be able to lead your organization into a successful QbD implementation.

You will learn:

Why QbD risk assessment is critical to the success of your QbD initiative

How to prevent the common mistakes QbD practitioners make (which may lead to QbD failure)

How to effectively facilitate risk assessments at the development stage where there are many unknowns and uncertainties

How to tie QbD risk assessment to Design Space studies.

What to focus on to get the most out of a risk assessment exercise

How QbD risk assessment fits in a QbD project.

Design space definition under QbD context

How to obtain design space with manufacturing data

How to use design space for biopharmaceutical application.

Participants will use Lean QbD Risk Assessment Software designed for Quality by Design projects. The course will utilize FDA case studies and an interactive project to simulate and practice QbD risk assessment.  If you properly conduct QbD Risk Assessment, then it will serve as a compass for design space studies. We will learn how to generate and prioritize process parameters to study, which connects to the QbD Design Space. QbD Risk assessment should be able to answer, “Which parameters affect the patients the most?”