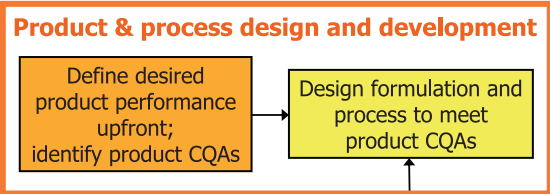
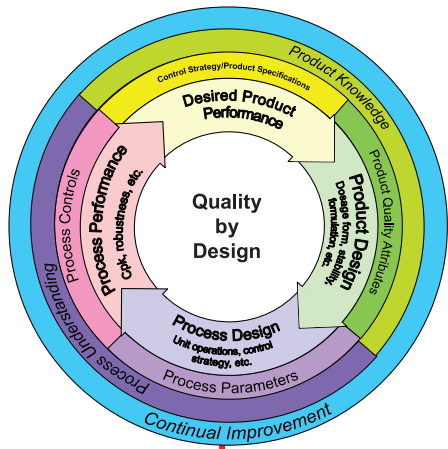
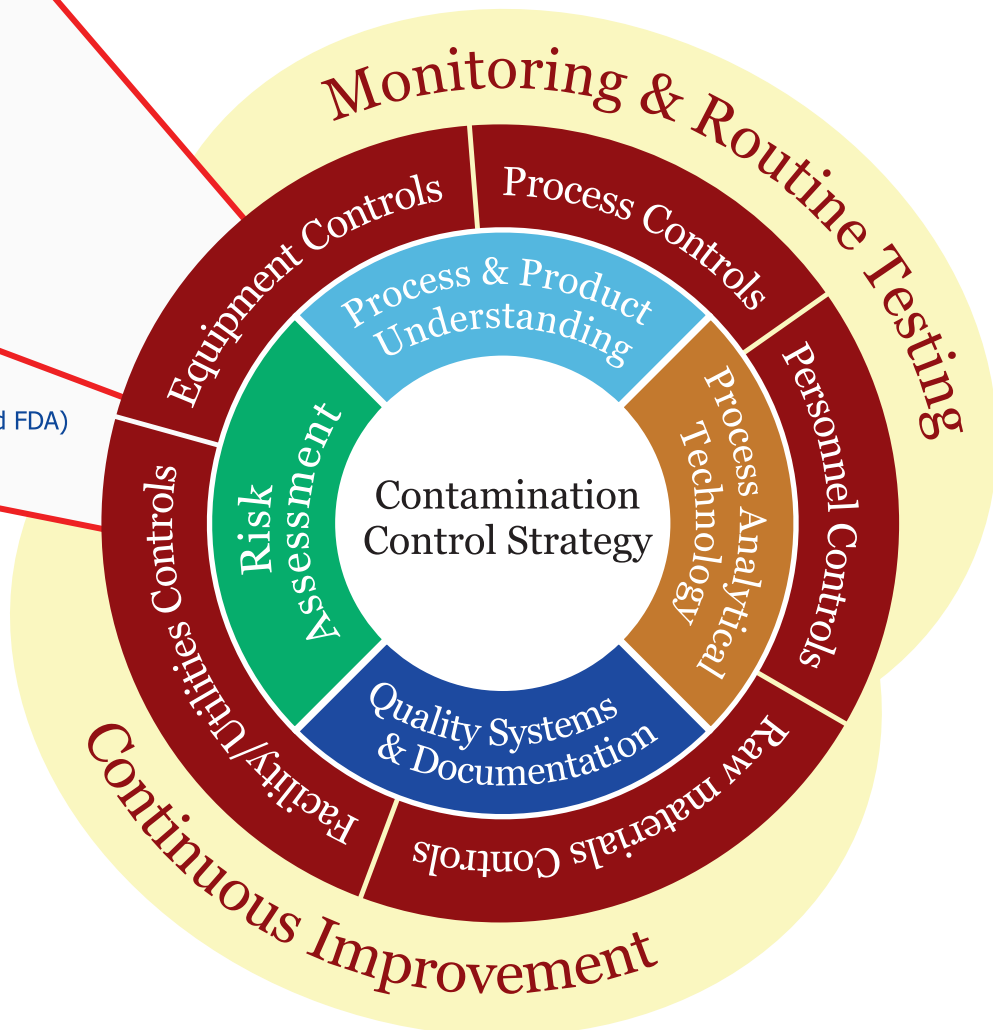


Contamination Control by Design (CCbD) ©



QbD System
(as defined by ICH and FDA)



Contamination Control is an integral part of the product control strategy and the current QbD approach. As such, it is important to integrate the concepts of Process & Product Understanding, Risk Assessment and PAT into the design of the contamination control program. Our model of CCbD uses as a reference point the QbD system wheel. It expands the QbD concept into more specific elements that are directly associated with the design of contamination control programs. It emphasizes the need to address contamination control issues as early in the product development life cycle as possible.