

DESIGN FOR FORMULATION

Formulators must deliver:

A product that meets the business brief

A manufacturing process that works first time and every time

Compliance with regulatory requirements

GETTING STARTED

Before you go into the lab:

Customer promise and technical brief

(what will you deliver?)

What do you already know?

What do you need to find out?

Communicate

Risk assessment



LABORATORY WORK

Define critical quality attributes

Design of experiments

Starting materials

Process parameters

Risk assessment

PILOT SCALE

Process design

Scale up

Availability

Process stretch

Process envelope

Process qualification and validation

Risk assessment



MANUFACTURE

Prove that the process:

Is robust and controlled

Is suitable for routine commercial manufacture

Has an effective control strategy

EXPLOITING THE KNOWLEDGE

Continuous improvement

Future proofing

Learning for future products

Future flexibility

Securing the knowledge base

