The elements of QbD consists of the following parameters:

1. Quality Target Product Profile (QTPP): Include dosage form, delivery systems, dosage strength(s), and so on. It is a prospective summary of quality characteristics of a drug product to be achieved, taking into account dosage strength(s) and container closure system of the drug product, together with the attributes affecting pharmacokinetic characteristics (e.g., dissolution, aerodynamic performance) and drug product quality criteria (e.g., sterility, purity, stability and drug release) appropriate for the intended marketed product.
2. Critical Quality Attributes (CQAs): Include physical, chemical, biological, or microbiological properties or characteristics of an output material including finished drug product. Potential drug product CQAs derived from the QTPP and/or prior knowledge are used to guide the product and process development and they should be within an appropriate limit, range, or distribution to ensure the desired product quality.
3. Critical Material Attributes (CMAs): Include physical, chemical, biological, or microbiological properties or characteristics of an input material. CMAs should be within an appropriate limit, range, or distribution to ensure the desired quality of that drug substance, excipient, or in-process material.
4. Critical Process Parameters (CPPs): Parameters monitored before or in process that significantly influence the appearance, impurity, and yield of final product.

This chapter will focus on technologies and suggest paradigms to broadly accomplish the development of robust solid dosage formulations and process understanding for future generations of new water-insoluble drug products.

PHASE I STRATEGIES FOR DRUG PRODUCT MANUFACTURING OF WATER-INSOLUBLE NEW CHEMICAL ENTITIES

Usually, the goal in the early phase of drug development is to minimize resource commitment and simplify the assessment of new chemical entities (NCEs) in the clinic. The dosage form and manufacturing strategies should support the objective of a minimalistic approach. In this model, the recommendation is to screen as many NCEs as possible, as quickly as possible, with minimal resource. To be successful in achieving this objective, businesses need to dedicate themselves to developing standardized methodologies for developing dosage forms through supporting good manufacturing practices (GMP) procedures for the water-insoluble drugs.

During Phase I studies, healthy volunteers are administered with a single dose of an investigational drug, and each receives only one dose. The study may or may not be placebo controlled. The starting dose is generally a large factor below the expected efficacious dose (i.e., no observable adverse effect level [NOEL] × safety margin). The dose is raised only after ascertaining that no adverse effects are observed. The new dose is generally administered to a different volunteer. The doses are raised until safety becomes an issue. The pharmacokinetic ADME data on the NCE is gathered by determining the plasma levels of drug after administering the dose.

The next stage of assessment is a multidose tolerance (MDT) study. The objective of this study is to assess pharmacodynamic and pharmacokinetic effects and to collect data for any adverse event observed. For this assessment, a range of doses is administered with placebo control to healthy volunteers for 7–14 days. The intention of these studies is to assess any potential saturation of metabolism.

To accomplish the single-dose and MDT studies mentioned earlier, the dosage form selected should encompass the range of doses desired for the duration of study with flexibility required for changing doses. Extemporaneous prescription compounding in clinics is one approach to provide