GreyRigge Associates Ltd.

CMC & Manufacturing

1. Good Manufacturing Practice

Good Manufacturing Practice (GMP) ensures that manufacturing processes meet defined quality standards. This includes documentation, validated procedures, trained personnel and controlled environments. The GMP framework helps maintain compliance and data integrity, as well as safety. It also helps ensure that processes perform as intended over time.

2. Pure & Potent Product

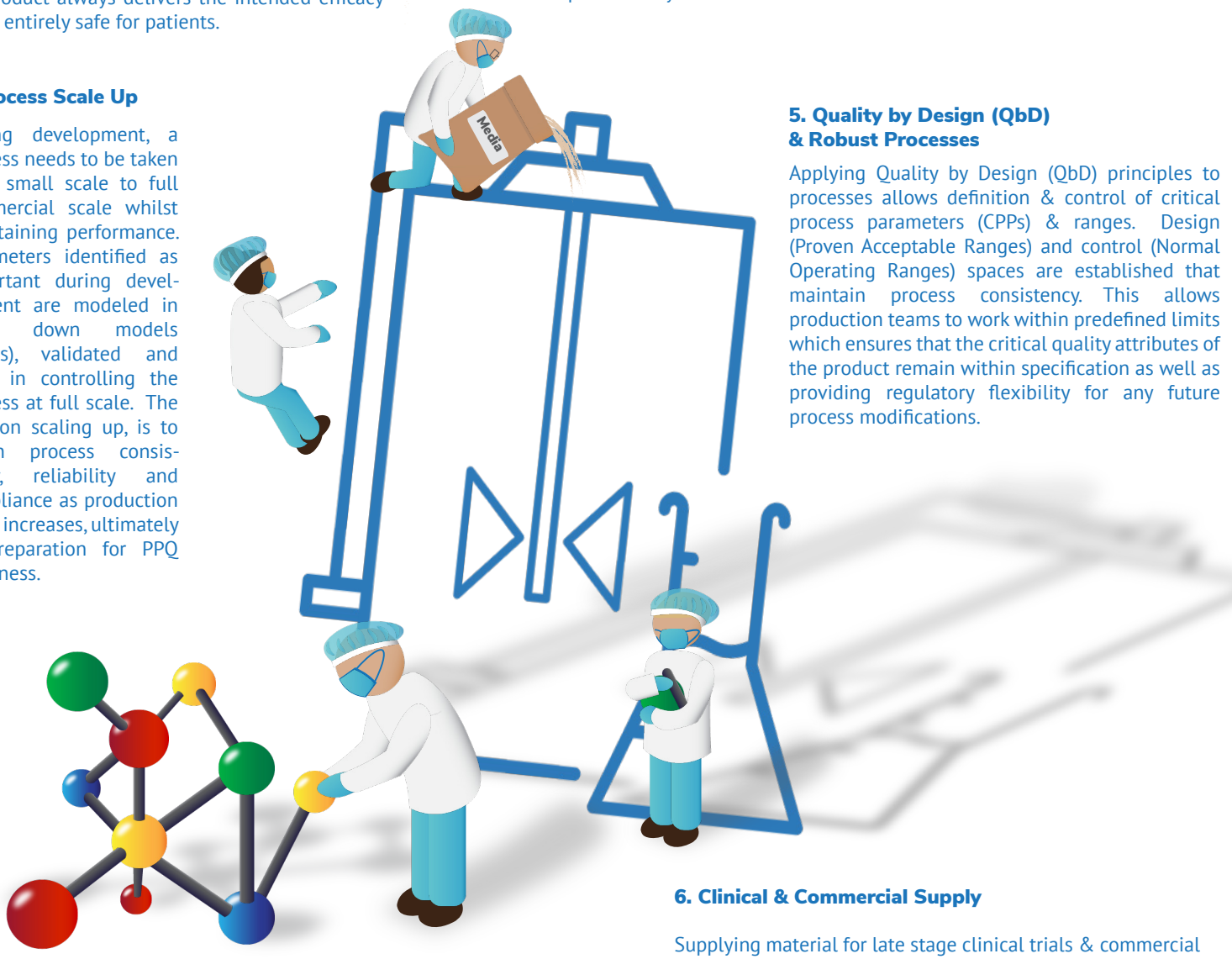
Product purity and potency are assessed at multiple stages of development using analytical and/or Quality Control methods. The focus is to ensure that the product's active substance consistently meets its required specifications for identity, strength and purity. This guarantees that the product always delivers the intended efficacy and is entirely safe for patients.

3. Process Characterisation

Process characterisation involves identifying and understanding the impacts of critical process parameters (CPPs), or inputs, on the critical quality attributes (CQAs) of the product, or outputs. Data from scale-down models (SDMs) and experimentation inform control strategies. This builds a robust knowledge base, supporting decision-making as well as process performance qualification (PPQ), also called process validation, across the product development lifecycle.

4. Process Scale Up

During development, a process needs to be taken from small scale to full commercial scale whilst maintaining performance. Parameters identified as important during development are modeled in scale down models (SDMs), validated and used in controlling the process at full scale. The aim, on scaling up, is to retain process consistency, reliability and compliance as production scale increases, ultimately in preparation for PPQ readiness.



5. Quality by Design (QbD) & Robust Processes

Applying Quality by Design (QbD) principles to processes allows definition & control of critical process parameters (CPPs) & ranges. Design (Proven Acceptable Ranges) and control (Normal Operating Ranges) spaces are established that maintain process consistency. This allows production teams to work within predefined limits which ensures that the critical quality attributes of the product remain within specification as well as providing regulatory flexibility for any future process modifications.

6. Clinical & Commercial Supply

Supplying material for late stage clinical trials & commercial distribution requires validated & robust processes with clear control and traceability from Manufacturing to Clinical administration. The goal is to ensure efficient batch-to-batch consistency that is in compliance with global standards, enabling reliable production and timely supply of product, whether for late stage clinical trials or for commercial supply.