PLG
ProductLifeGroup

Quality & Compliance

Navigating the labyrinth of the manufacturing process

The manufacturing process is the foundation of all pharmaceutical products and their clinical versions. These early-stage processes influence the product life cycle and directly relate to late-stage activities covered by GMP operations, safety and pharmacovigilance. Therefore, Chemistry, Manufacturing & Control (CMC) professionals must have an intimate understanding of the regulations and how the different components of the system interact to produce quality medications safe for public use.

Within the Quality and Compliance (Q&C) space,

we, ProductLife Group, ensure that your commercial activities are running according to cGMP regulations in a robust and reproductible way.

Q&C teams operate from, but are not limited to, GMP design review of new manufacturing facilities, implementation of QMS for manufacturing, distribution activities and operational quality support.

Quality regulations are also geographically specified on the market where the product is intended to be sold.

Facility GMP design review & Qualification services

- Review of layouts, process & personnel flows, cleanrooms, clean utilities
- CQV strategy definition
- Equipment Selection, Commissioning Qualification and Validation
- Qualification Non-conformities management

Quality Management System (QMS)

- QMS design for manufacturing and distributions facilities
- Define and write Quality manuals, policies, procedures, work instructions, forms and records
- QMS implementation with Training/Coaching of personnel

Training & Coaching

- Training on GMP, GDP & QA topics
- Training for Inspection readiness
- On-site coaching, mentoring of your teams, change management and sustainable improvement

Services

Computer system validation & integrity services

- Definition and implementation of IS/IT validation
- strategies by a risk-based approach
- Remediation of Data Integrity issues
- Periodic validation of IT/IS systems

GMP & GDP Quality services

- Inspection readiness
- On-site operational support: deviations, CAPA, claims, Change Control, OOS, OOT Management
- Batch records review
- Quality Remediation plans
- Outsourcing of Product Quality Reviews

A light through the Labyrinth: what PLG can offer

Facility design review & qualifications

PLG's professionals, in conjunction with our experienced project management team, support facility design review considering cGMP regulations, the definition of Qualification strategies, equipment selection, commissioning and qualification of cleanrooms, HVAC, utilities, process equipment and validation of process, cleaning and sterilization processes.

Quality Management System (QMS)

To ensure your facility is ready for its manufacturing or distribution services and meets the latest regulatory standards, PLG support in designing and implementing your QMS: For existing systems, ProductLife Group can conduct a QMS assessment, define and implement a roadmap for QMS optimization. For new systems, PLG can design, set up and implement a new QMS, including preparing all sets of documents (quality manuals, policies, SOPS, WI, forms and records.)

Computer system validation and data integrity services

With multi-faceted experts, PLG can assess, define strategies, validate and remediate your Information Technology-related quality challenges tailored to your company's needs.

Quality assurance GMP & GDP services

To keep up with industry standards, we manage your backlog of deviations, CAPA, claims, OOS and CC. Furthermore, we define and implement sustainable governance, training and coaching your teams to help you regain control of your quality processes. We also support your batch record reviews and conduct your Product Quality reviews.

Training and coaching services

ProductLife Group's experts train and coach your operational teams in change management principles and continuous improvement processes to increase your departments' global performance.

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