Regulatory Policy

DND*i* POLICIES

DNDi
Drugs for Neglected Diseases initiative

DND*i* operates in a highly regulated environment. From the earliest phases of the drug development process, registration requirements will be taken into account and all R&D will be performed according to international standards.

The research, development, and supply of a novel therapy invariably results in a certain level of risk. Quality is a central component associated with all of the risks: quality of the R&D activities performed, quality of the developed substances, and quality of the final product. Therefore, project-associated quality and safety from screening through clinical development and up to the implementation phase are a key success factors for DND*i*.

DND*i* quality control/quality assurance (QC/QA) aims to build a global set of internal and appropriate standardized operating procedures (SOPs) that will cover all stages of drug development and are based on the International Conference Harmonisation (ICH) and the Organisation for Economic Co-operation and Development (OECD) recommendations. Both GDP (Good Documentation Practice) and GRP (Good Reporting Practice) are essential.

GDP may include (but is not limited to):

- Quality assurance documents (policies, guidelines, and SOPs);
- Product specifications (sampling, regulatory specifications);
- Materials specifications (raw materials, process materials);
- Manufacturing documents (formulation/process specifications);
- Testing documents (test methods) based on risk audit processes.

GRP will be set up with subcontracting academic or private laboratories to monitor experiments and projects. Reporting done in a standard format as part of SOPs, for each stage of product development and for all subcontractors, will allow for follow-up with respect to the design, processes, and format of the reporting.

- At the preclinical level, quality assurance will focus on appropriately interpreting OECD guidelines for GLP (Good Laboratory Practice) and on adapting GSP (Good Scientific Practice) and GDP.
- During clinical development, translation of GCP (Good Clinical Practice) and GCLP (Good Clinical Laboratory Practice) into specific internal SOPs will be critical milestones.
- Chemistry, manufacturing, and controls development will rely on effective and efficient GMP(Good Manufacturing Practice) SOPs to sustain a “regulatory” level of quality product development and registration.

GDP, GRP, GCP (Phase IV) and GMP will continue through the implementation period.