



Clinical Informatics

FACTSHEET



Managing Manufacturing Processes

The Clinicopia Process Execution System ensures that pharmaceutical and biotech companies are better able to manage their resources within the clinical manufacturing and packaging process, as well as comply with strict federal regulations and GMP standards. The Process Execution System provides recipe management, process management, electronic batch records, document management and resource scheduling.

Recipe Management

The Recipe Manager is used to create, control and release master data for production planning and scheduling. Recipes include information about the products and components of a process, the process steps to be executed, and the resources required for production.

Process Management

Process Management gives decision makers the ability to plan, schedule and associate resources for the recipe specified for the job. While manufacturing or packaging, users can perform material dispensing using Weigh and Dispense and execute the work order as per the Master Batch Record.

Electronic Batch Records (EBR)

The entire production life cycle of an individual job is captured electronically in an EBR. With EBRs, managers can efficiently review their process data, conduct statistical analysis and distinguish possible bottlenecks and downtime.

Resource Scheduling

Decision makers can study proposed resource allocation and make adjustments to maximize and optimize the utilization of resources.

Product Benefits

- Decreased labor costs and waste through advanced production planning
- Increased profitability and consistency through a better level of inventory control and margin visibility

- Increased efficiencies due to faster and more accurate electronic records
- Compliance with FDA 21 CFR Part 11, process execution regulations and GMP standards

The Process Execution System can be seamlessly integrated into the Clinicopia Suite.

Key Features:

- Multiple revisions of master recipe possible
- Ability to associate previously modified recipes to similar jobs
- Graphical representation of processes
- Scheduling module
- Weigh and dispense
- Ability to preview EBRs at any stage
- Resource availability reports
- Inventory reconciliation
- Fully electronic-signature enabled
- Comprehensive audit trails
- Sliding scale quality class management
- 21 CFR Part 11 and GMP compliant

Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

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Engineering a better drug development process.