Modular-Lab Cassettes

Services for Customization and Process Development

Development of automated processes and manufacturing of cassettes according to customer specifications

General Information

Eckert & Ziegler Eurotope GmbH offers a wide range of customization services for cassettes using their proprietary Modular-Lab technology. Customers benefit from a proven and reliable technology, the option to use parts based on their own development (e.g. filters and cartridges) according to their specifications and the long-term experience in the automation of manual processes. Each development for the automated tracer production covers basic process steps including tech-transfer, feasibility, optimization and confirmation of performance by execution of master-batches, accompanied by a quality control validation.
The development results in the design of a Modular-Lab synthesis cassette and associated software process, both ensuring reproducible tracer production runs. Synthesis cassettes will be assembled under GMP-compliant conditions in Eckert & Ziegler's clean rooms.
Extensive documentation will support the registration of a potential clinical trial and its safe conduct, facilitating interaction with competent authorities. Required changes and improvements can be easily introduced by full control of the in-house production and quality assurance department. All services can be customized and extended according to individual specifications.

Offered customization services may include:

- **Process development** for automated synthesis on Modular-Lab PharmTracer, Modular-Lab eazy or KitLab for alpha, beta and gamma emitting radiotracers including hardware, software, cassette, reagents, manuals, quality control process and validation for easy transfer to production sites
- **Framework agreements** for preferred supply and production slots
- **Quality assurance agreements** providing auditing rights, additional validation, test samples and more
- **Certification of suitability** for raw materials
- **Enhanced incoming goods inspections** according to predefined specifications
- **Shelf-life studies** to ensure sterility or performance
- **In-process monitoring of production** according to individual checklists
- **Extractables/Leachables studies** using partner network
- **Enhanced documentation** including Certificate of Analysis (CoA) and conformity (CoC) for batches and reagents, proof of sterilization, batch reports and more
- **Enhanced GMP compliance** using barcode plausibility check in the application software

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