Qualification and training of the staff

Job description: Validation & Transfer Technician

Position in organization:

- Department: Laboratory R&D (Analytical Development)
- Reporting to: Laboratory Manager
- Staff in charge: -
- Location: Esplugues de Llobregat (Barcelona)

Education:

- Degree in health sciences, preferably in Chemistry
- Preferably Master's degree in Analytical Chemistry or Pharmaceutical Industry.
- Excellent level of scientific and business English, spoken, reading and written.

Skills:

- Self-sufficient, critical, disciplined, confident, hard working, creative, motivated, proactive, dynamic, methodical, organized and decisive.
- Strong analytical skills and problem solving.
- Highly responsible and capable to work under pressure to meet deadlines.
- Excellent organizational, planning and time management skills, to achieve project timelines.
- Detail oriented professional with good communication skills.
- Ability to absorb, digest and related detailed scientific, quality and regulatory information.
- Supportive and able to build effective working relationships throughout the organization.
- Ability to prioritize multiple tasks and execute projects on time in a fast-paced environment.
- Ability to use and generate documentation in English.
- Ability to increase technical knowledge and apply new skills.
- Availability to travel

Previous experience required:

- Minimum 2-3 years' experience in analytical development in GLP/GMP environment, showing proven experience in the development and validation of most of the following analytical methods: HPLC, UPLC, LC-MS, GC, UV-Vis, DSC, PSD, potentiometric titration, IR, KF Titration and Dissolution tests.
- Experience in writing and review Transfers & Validation Protocols and Reports of Analytical Methods for different CRO's or CMO's.
- Very valuable to have knowledge of international guidelines EMEA, FDA, ICH, ANVISA and ISO.
- Experience MS Office

Roles and responsabilities:

- Writing Protocols & Reports of analytical validation of new analytical methods for active pharmaceutical ingredient and finished dosage forms.
- Writing Protocols & Reports of transfers analytical methods between different Sites for active pharmaceutical ingredient and finished dosage forms.
- Management and review of the documentation provide by CRO's and CMO's in reference to the analytical validations & transfers activities.
- Management of all the material (such standards, samples of finish product, HPLC Columns,etc) needed to complete the activities. (Validations or Transfers)
- Follow-up of all the tasks that are carrying out.
- Collect external product methods of analysis current version and edit Galenicum MoA's.
- Act as an interlocutor between the transferring laboratory and receiving laboratory.
- Writing of technical reports and SOP's (Standards Operating Procedures).
- Propose improvement flows for the department.
- Technically guide the staff of whom in charge and provide answers and support to allow them to generate valuable results.
- Responsibility to replies to deficiency letters.
- Motivational skills to allow your team to achieve better results with time.
- Be focused on accomplishing the company goals

Occupant Information:

Initial Date:

Name and Surname:

Address:

Telephone:

AUTHOR	APPROVED BY COLLABORATOR	APPROVED BY HR
Name:	Name:	Name:
Date:	Date:	Date:
Signature:	Signature:	Signature: