

Team QC-ASAT Transfer & Validation Small Molecules (Drug Substance/Drug Product)

The Quality Control (QC) ASAT (Analytical Science And Technology) supports in its main task any analytical activities necessary for the introduction of a new product Drug Substance as well as Drug Product. Furthermore, the group is responsible for analytical transfer projects (In & Out).

This includes the following activities:

- Analytical launches of new pharmaceutical products and analytical transfers of commercial products. This includes:
 - Managing various interfaces within Quality Control, Analytical Development, Global Functions, external contract manufacturers as well as other Roche sites (e.g. Shanghai, San Francisco)
 - When introducing new drug substances, we independently perform all necessary validation analyses in our laboratory in Basel. In doing so, we work closely with analytical development and commercial release.
- Creation and modification of analytical methods as well as specifications for raw materials, drug substances and drug products and evaluation of regulatory impact (gap assessments)
- Trending of data from release analytics using software tools (BaLi and reMIX)
- Screening of changes in pharmacopoeias and evaluating the impact on our analytical regulations
- Various other projects such as maintaining the Google Team Site and Virtual Books (Documentum regulatory directory).

A university degree (bachelor's or master's degree) in chemistry, pharmacy, pharmaceutical technology or a related natural science field and good English skills are required to support the team.

Enrollment in a university is required.

The preferred start date of the internship would be February 2022 or by arrangement.

Duration of the internship: 6-12 months

If you are interested, please send your resume to the following contact:

Dr. Anika Hubrich

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