



Fabiola Ortega, RAC

Regulatory Affairs Consultant

EXPERIENCE:

- Biological lab analyst, Quality Control, Schering-Plough, S.A. De C.V. - 2010 to 2011

AREAS OF EXPERTISE:

Analytics techniques of raw material and finished national and international product:

- Sterility
- Microbial limits
- Endotoxin analysis
- Analysis of WFI and purified water
- Biological essays
- Biotin analysis
- Supervision of sterile and non-sterile areas
- Simulation of aseptic process

Disciplines:

- Standard Operating Procedures, Working Procedures and Operating Manuals (issuing and updating)
- Execute the register of activities within the area in accordance with GMP's, GCP's, SOP's and WP's in force
- Preparation of reports of activities, archive and handle of documentation
- Supervision and verification of results within the parameters
- Issue and updating of certificates of analysis for national and international product in LIMS
- Knowledge of NOM 059, NOM 072, NOM 073, NOM 137

EDUCATION:

- Biopharmaceutical Chemist, Chemistry Faculty, CU, UNAM, México, D.F.

TRAINING AND CERTIFICATIONS:

- Good Manufacturing Practices (cGMP's)

PUBLICATIONS AND PRESENTATIONS:

- Lecturer at the "2as Jornadas Apícolas en Veterinaria" with the subject Composición química de un propóleos recolectado en la zona rural del D.F.UNAM (2010)