Taher Glal ahmed

validation supervisor

My Contact

taher.glal53@gmail.com

+201156458842

Egypt /Cairo / Helwan

Hard Skill

- Technical skills
- Data analysis skills.
- Microsoft office
- spoken languages.

Soft Skill

- Communication
- attention in details
- Teamwork
- Leadership
- Problem-solving

Education Background

- Bachelor's degree in Chemistry
- International computer driving license (ICDL) in 2010
- statistical analysis (Data analysis) in 2022
- CTD and eCTD training course in 2020

About Me

- Date Of Birth:15\7\1990.
- Address: Helwan , Cairo
- Gender: Male.
- Email Address: taher.glal53@gmail.com
- Military: Exemption
- Nationality: Egyptian

Professional Experience:

validation supervisor in Rotabiogen factory-Hefny pharma group (HPG) from Aug-2022 till Now.

Key responsibilities:

- conduct & Review process validation protocols and generate process validation reports (PVR) with statistical analysis charts of products (Vail & ampoule lines)
- conduct & review media fill batch record which conduct every 6 month for (vial and ampoule) lines then generate report for media fill (vial & ampoule)lines and review also evaluation & environmental data coming from microbiology department.
- conduct evaluation cleaning validation for new products with worst case matrix for product A selection & product B selection in cleaning validation protocol.
- conduct & review thermal mapping qualification reports of terminal Autoclave & (vial, ampoule autoclaves) for machine parts and garments then generate reports for coldest and hottest points in the autoclaves .
- conduct IQ , OQ & performance qualification for Blistering Machine (tablet &capsule) products
- conduct & review performance qualification reports of thermal mapping storage area and cold rooms.
- conduct & review performance qualification reports steam in place (SIP) of preparation and filtration tanks.
- conduct & review (HVAC , LAFS & pass boxes) performance qualification reports in production and Microbiology department.
- conduct & review tunnel qualification reports of (Ampoule, vial).
- conduct & review Annual Validation Plan for (process validation of products, HVAC system , LAFS, Pass boxes , SIP of tanks , Autoclaves , Media fill , Warehouse , cold rooms, Steam Quality Tests ,Compressed Air Tests ,Compressed Nitrogen Tests , cleaning validation)
- review conducting calibration plan for (pressure gauges , temp sensors, digital balances, thermal ovens , etc.)
- participate in deviation & change control related to Equipment qualification or process validation .

validation senior in Rotabiogen factory-Hefny pharma group (HPG) from jan-2022to July 2022

Key responsibilities:

- participate in creation process validation protocols and generate process validation reports (PVR) with statistical analysis charts of products (Vail & ampoule lines)

- participate in creation media fill protocols (vial and ampoule) lines and review batch record which conduct every 6 month then generate report for media fill (vial & ampoule lines).

- participate in conduct cleaning validation for worst case matrix for product A selection & product B selection in cleaning validation protocol within three successful cycles (vial & ampoule lines) and review QC for swap and rinse (API residue) reports & micro results for (endotoxin & Bioburden) for Rinse and Bioburden for swaps reports.
- conduct & review thermal mapping qualification reports of terminal Autoclave & (vial, ampoule autoclaves) for machine parts and garments then generate reports for coldest and hottest points in the autoclaves .
- conduct & review performance qualification reports of thermal mapping storage area and cold rooms.
- conduct & review performance qualification reports steam in place (SIP) of preparation and filtration tanks.
- participate in conducting (HVAC , LAFS & pass boxes) performance qualification reports in production and Microbiology department.
- conduct & review tunnel qualification reports of (Ampoule, vial).
- participate in conducting Annual Validation Plan for (process validation of products, HVAC system , LAFS, Pass boxes , SIP of tanks , Autoclaves , Media fill , Warehouse , cold rooms, Steam Quality Tests ,Compressed Air Tests ,Compressed Nitrogen Tests , cleaning validation)
- participate in conducting calibration plan for (pressure gauges , temp sensors, digital balances, thermal ovens , etc.)
- participate in deviation & change control related to Equipment qualification or process validation .

validation specialist in Rotabiogen factory-Hefny pharma group (HPG) from jan-2021 to jan-2022

Key responsibilities:

- conduct IQ , OQ & performance qualification of LAFs and Pass Boxes
- participate in IQ , OQ & performance qualification of HVAC system
- participate in IQ , OQ & performance qualification of tank 50 Liter & tank 100 Liter (dedicated Tanks) for hazard product (50L) or small batch size of some products (100L) & manufacturing tank , filtration tanks
- conduct & review IQ, OQ & conduct performance qualification terminal Autoclave & participate in performance qualification of (vial, ampoule autoclaves) for machine parts and garments then generate reports for coldest and hottest points in the autoclaves .
- conduct & review performance qualification of thermal mapping storage area and cold rooms .
- conduct & review performance qualification reports steam in place (SIP) of preparation and filtration tanks.
- participate in conducting calibration plan for (pressure gauges , temp sensors, digital balances, thermal ovens , etc.)

Documentation specialist in Rotabiogen factory-Hefny pharma group (HPG) from 2018 to 2021

Key responsibilities:

- create CTD files for products and collecting data required for complete CTD files sane sent them to African countries.
- following and covered CTD files comments coming from Tanzania and Uganda
- create Bill of material for (API , Excipients & packaging materials) on ERP system and make reports .
- create the License's requirements for pilot and production batches according to (supplier variation , factory variation, packaging material variation)
- Evaluation of all API material before allow purchasing by supply chain department.
- make specification for APIs and Excipients according to USP & Eu pharmacopeia.
- following price updates then upload on products in ERP system.
- review & monitor production plans on ERP system.
- review supplier approval, factory approval, primary packaging approval on ERP system.
- review production plans and supply API quantity required .

quality control in Ibrahim EL-Issa Salt factory in Saudi Arabia from 2015 -2017

Key responsibilities:

- conduct analysis to salt types to give Assay of sodium chloride, moisture of salt sample & calcium , magnesium in salt sample , quantity of impurities in salt sample.
- prepare bulk solution for Iodine and Sodium ferrocyanide as anti-caking and monitor the quantity add per each Kg of salt by pump allowance .
- monitor manufacturing steps from (raw material adding in feeder to finished product) and additives for salt during manufacture.
- prepare all chemicals required in Lab and make daily report for all types of salt.
- arrangement warehouse packaging &storage condition.

Documentation specialist in Rotabiogen factory-Hefny pharma group (HPG) from 2013 to 2015

Key responsibilities:

- Responsible for preparation and submission of Analytical dossiers to NODCAR.
- following up the comments reply during registration of Analytical dossiers to NODCAR till the files accepted and take approval form NODCAR .
- Follow up Raw materials , and products in inspection department in NODCAR till take NODCAR approvals and release products.
- Follow up any change needed in any product such as change in pack, formula or name.
- create Drug Master files and monitoring files of pharmaceutical products.
- review stability files issued from quality control department.