Dr.Nadia Ghazal CV

Direct contact number:
00971568626488

LinkedIn: https://www.linkedin.com/in/nadia-ghazal-076284

SUMMARY OF QUALIFICATIONS

1- Gathered over 34 years of experience in pharmaceutical product development and in driving cGXP compliance in drug development , manufacturing and distribution (this includes cGMP, cGLP, and cGSDP) for accreditation of pharmaceutical manufacturers to USFDA/EMEA/MHRA and GCC cGMP.
2- Long years of experience in products development, manufacturing and registration for regular, biotechnology and oncology products.
3- Gained a significant track record for dynamic involvement in launching systems in pharmaceuticals regular , biotechnology and oncology finished products development, registration, storage and distribution aligned to current EU/USFDA cGMP/GSDP standards, and current GSDP standards.
4- Building Quality Management systems for pharmaceuticals manufacturing, storage and distribution .Training the pharmaceuticals manufacturing employees, regulatory body staff and inspectors, and pharmacy graduate students on all GMP aspects including validation and qualification work. Helping pharmaceuticals manufacturers to maintain the compliance status for the future.
5- Secured significant approvals related to pharmaceutical, biotechnology industry benchmarks.
6- Involved in significant laboratory, manufacturing facilities, drug stores designs . Proper work system establishment .
7- Developing competitive pharmaceutical dosage forms of high quality including super bioequivalent drug products.
8- Incubated new lines of business for the industry including injectables, regular, vaccines, biotechnology and oncology products production , testing and registration .
9- Focused on training employees on technical issues and cGMP/GSDP/GCCP/GVSM regulations.
10- Worked with supplier's evaluation and setting specifications in line with European guidelines.
11- Directly involved with production planning, trouble shooting and process optimization.
12- Trained MOH staff in KSA, Oman, Lybia, Iraq, Jordan, Lebanon on GMP compliance and inspection .
13-Training MOH staff in KSA and other MENA countries on good practices to manufacture and
distribute vaccines (Good Vaccines Management practices).
14-Conducting pre-inspections on pharmaceuticals manufacturers and distributors to ensure compliance to international GMP standards and readiness for the inspections . Providing GAP assessment reports and managing CAPA with customers to ensure minimal variations from these guidelines during and after the inspection.

Education background

1. PhD degree in Pharmacy (pharmaceutical technology), Bath University, 2005
2. M-Phil degree in Pharmacy (biotechnology) , Bath University, 2000
3. B.Sc. in Pharmacy (with honours), University of Science & Technology, 1990 (with honors)

MBERSHIP:

Parenteral Drug Association member PDA
Invited by USP to be a member in the Drug Storage Guidelines Expert Committee
JAPM
AMCHA
MECCA- Founder

PROFESSIONAL EXPERIENCE

I- **Pharmaceuticals product development and GXP compliance consultant: 2007-today**

Naratech pharma consultancy : Founder 2007-2017
Kanata Pharma-Canada : Founder 2016-today
Lavida Pharma-Portugal: Founder 2020-today

Drug Manufacturing-Lead project management of upgrading the standards for pharmaceuticals development , manufacturing and registration in companies in Europe/MENA/ and USA according to current FDA/EU/WHO/ HC/MHRA GMP guidelines .
Drug storage and distribution-Lead project management for upgrading the standards of pharmaceuticals storage and distribution according to current GSDP guidelines

2- Founder of Middle East Cold Chain Association "MECCA" in the Middle East, for the purpose to develop GSDP standards for MENA region that will mitigate the risks in our area and at the same time go parallel with the world wide GSDP standards, specially USP, EMEA and WHO.

MAIN ACCOMPLISHMENTS:

Worked as a consultant for more than 20 pharmaceuticals manufacturing and distributing companies in MENA region, Europe , Canada and USA . Consultation covered the below areas:

1-Project leader , leading Pharma/biotechnology companies teams to USFDA GMP approval .
2- Establishment of the first oncology facility in the MENA (solid dosage forms flexible containment and fixed injectables containment), together with a state of the art oncology testing contained lab).
3- Developing oncology products (solid and injectables dosage forms) and registration files preparation.
4- Leading Eu cGMP certification of Pharma/biotechnology companies
5- Appointed as a QP for products files registration and submission to FDA, EMEA
6-Assisting development of more than 65 pharmaceutical products in different dosage forms.
7- Assisted many companies in MENA to certify facilities to SFDA, GCC ,and PICs.

8- Conducted training in the area of GMP/GLP/GSDP to regulatory bodies and inspectors in MENA region.
9-Conducted cGMP inspections for over than 35 drug stores in MENA , and more than 10 Pharmaceutical manufacturing facilities in MENA and Europe.
10-Conducting trouble shooting and process optimization for more than 30 products for different customers.
11-Suppliers evaluation and qualification , and DMF revisions and evaluation according to FDA/EU and GCC regulatory standards.

Appointed as Technical Consultant to Chanelle Pharmaceuticals, Ireland, 2002-2004.
Worked on quality system development for Irish Medicine Board GMP approval.

III- APM /ADVANCED PHARMA, Jordan-Acquired later by HIKMA International .

Technical Director 1995- 2007

-**Responsibilities**:

1. Manage the R&D department, production facilities at three sites (solid, liquid, semi-solid and sterile production), Production planning department, engineering department, as well as EU and USA , and MENA registration departments.
2. Manage regular and oncology products development, and ensure proper development , registration files preparation and manufacturing of the pharmaceutical products in line with cGMP .
3. Undertake follow up of all technical activities in the technical departments.
4. Trouble shooting in production areas .
5. Management of new projects in the company including new product lines such as sterile production and oncology production..
6. Launched robust systems in the Technical departments to ensure quality in product and delivery adhering to timelines.
7- Upgraded the existing facilities according to EU cGMP.
8- Initiated proper technical data documentation in the company
9- Manage the R&D and Production department including production planning.
10- Ensure proper development and manufacture of pharmaceutical products as per cGMP.
11- Supervise all technical activities in the technical departments.
12- Launch new product lines in the company including the oncology manufacturing, sterile pharmaceutical products manufacturing

IV- JPM Pharmaceuticals Industry

R&D Head, 1990-1995

Responsibilities:

1- Supervise the development of pharmaceutical dosage forms, including analysis ,formulation, pre-formulation and stability, according to current cGMP guidelines.

Other accomplishments:

1- Selected from JAPM as an internal consultant to do pre USFDA inspection on 6 pharmaceutical companies .
2- Established a complete GSDP and GCCP systems for drugstores, that was approved by the principals Roche, and Astra Zeneca, Novartis, and many other international companies.
3 -Document the systems in all areas of pharmaceuticals/biotechnology products manufacturing that comply to GMP.
4- Formulated registration files in tune with the CTD format (ICH guidelines) for products destined for Europe and USA.
5- Launched Oncology development lab, including the design of the isolators and monitoring of the environment.
6- Possess three years of experience as the Head of the Health Risk Assessment team.
7- Developed a product for Hoffmann La Roche, Basel/Switzerland.
8- Established the regular-products lab which comprised both equipment and personnel.
9- Selected production machines & established batch records documentation.

HONORS AND AWARDS

- B.Sc. in Pharmacy (with honours), University of Science & Technology, 1990

LANGUAGES

- English – Fluent
- Arabic – Fluent
- Portuguese - Born in Brazil

HOBBIES AND INTERESTS

- Reading, swimming, and traveling