FRANK P. WAGNER
[redacted]

RETIRED

- July 2016

PROFESSIONAL EXPERIENCE:

- Sr. GxP Compliance Auditor, AbbVie, R&D Quality Assurance (Abbott Laboratories until 1/1/2012)
  August 2008 through July 2016

Managed the timely execution of the AbbVie R&D global audit schedule. Performed compliance audits of third party clinical manufacturers and service and material providers per schedule or project timelines. Performed internal AbbVie R&D compliance audits per schedule. Performed risk based assessments of raw material suppliers. Ensured accuracy of the Approved Supplier List through regular reviews and updates. Ensured BSE/TSE and AQIS compliance for materials used in R&D Clinical manufacturing. Evaluated clinical filing dossiers versus technical reports to ensure accuracy. Performed due diligence activities in support of in-licensing agreements. Shared DEA and Customs coordinator responsibilities for AbbVie R&D.

- Senior Compliance Auditor, Abbott Laboratories, Global Pharmaceutical Operations
  October 2005 to August 2008

Managed the timely execution of supplier and third party manufacturer audit schedule. Project manager for over 300 of the approximately 1270 suppliers in the Global Pharmaceutical Operations Approved Supplier Database. As a member of the Global Pharmaceutical Operations Supplier Quality Assurance team, developed annual supplier assessment schedule, which included on-site audits, desk audits (quality questionnaires and history review) and annual supplier quality review. Performed on-site compliance audits as assigned. Processed supplier specification exceptions. Ensured accuracy of Approved Supplier Database through regular review. Provide Quality Assurance support for multiple high visibility new product launches and transfers.

- Senior Compliance Auditor, Abbott Laboratories, Global Pharmaceutical Operations
  February 2001 to October 2005

Performed compliance assessments on Active Pharmaceutical Ingredients manufactured by Global Pharmaceutical Operations. Using ICH Q7A as the primary guidance, specifically focusing on equipment, facilities, utilities, computer, and cleaning validation as well as cleaning procedures and utility performance. Identified and prioritized compliance issues to be forwarded to the remediation team. Provided follow-up and close out on issues that fell outside of the scope of the remediation team.

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- Senior Compliance Engineer, Abbott Chemical and Agricultural Products Division, Plant Engineering
  August 1997 to February 2001

Supervised a staff, consisting of two Engineers, two Engineering Technicians and up to five contract engineers. Was responsible for compliance support for equipment, facilities, utilities and controls systems in the North Chemical Manufacturing Area of Chemical and Agricultural Products Division. Support included; Management of Change for GMP, PSM, EPA and projects. Developed and executed Validation Master Plan annually and developed a 5 year Validation Master Plan. Ensured compliance through validation / qualification decisions, protocol development and review and approval of validations and qualifications.

- Senior Quality Engineer, Abbott Diagnostics Division, Site Validation
  February 1996 to August 1997

Supervised two Quality Engineers and one Quality Technician. Provided equipment, facility and utility validation / qualification support for Abbott Diagnostics Division, Lake County. Support included; validation / qualification decisions, protocol development, test execution, summarization of protocols, revalidation protocols and execution, review and approval of subordinates Engineering Change Authorizations and presentation of validation documentation to the FDA. Supported Regulatory Affairs via generation of Validation Summaries or ELA's. Reviewed RCE's for quality impact and provided documentation. Provided statistical support for Lake County Fill / Label operations.

- Quality Engineer, Abbott Diagnostics Division, Quality Systems
  February 1992 to February 1996

Provided validation support for Abbott Diagnostics Division. Support included; validation decisions, protocol development, test execution, summarization of protocols, revalidation protocols and execution. Supported Regulatory Affairs via generation of Validation Summaries or ELA's. Provided statistical support for Lake County Fill / Label operations.

- Senior Manufacturing Foreman, Abbott Laboratories, Hospital Products Division, Flexible Container Manufacturing
  June 1987 to February 1992

Supervised a crew of 44 hourly and non-exempt employees. Was responsible for packaging, sterilization and finishing within parenteral flexible container manufacturing operations. Managed HPD North Chicago laundry services and the Flex Production Work Order Office.

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- Maintenance Foreman, Abbott Laboratories, Hospital Products Division, Flexible Container Manufacturing Maintenance
  August 1985 to June 1987

Supervised a crew of 12 hourly and non-exempt employees. Responsible for three shifts of maintenance support of radio frequency subassembly operations, 1/86 to 6/87. Supervised a crew of 8 hourly and non-exempt employees. Responsible for two shifts of maintenance support for Irrigation Filling operation, 8/85 to 1/86.

- Engineering Technician, Abbott Laboratories, Product Engineering
  October 1980 to August 1985

Qualification of equipment and validation of processes related to new product introductions. Was responsible for qualification of new equipment. Developed, executed and summarized qualification protocols and engineering studies. Coordinated / managed large qualification projects.

EDUCATION

Bachelor of Science, May 1980
Northern Illinois University, DeKalb, IL.
College of Professional Studies, Department of Industry and Technology
Major: General Industry and Technology (Engineering)

CERTIFICATIONS / LICENSES / RELEVANT SEMINARS

- ASQ Certified Quality Auditor, Certificate #33835, Certification Date 12/03/2005
- GMP Audit Training – European Compliance Academy – October 2010
- PPGDVC-QA-00001EN: Combination Products Design Control / Design History File (DHF) Overview (7 May 2012)

EXTRACURRICULAR

Police Officer, Illinois Auxiliary Police, 1989-1997

REFERENCES

Will be supplied upon request