GXP Assure
Supporting GxP Compliance Worldwide

CURRICULUM VITAE

Katarina Thor

MSc Pharmacy
Senior Consultant

Recognised Areas of Expertise:

As a former Health Authority inspector, Katarina has conducted sponsor, vendor and site inspections globally for EMA, WHO and MPA including joint inspections with FDA. She has worked with all clinical trial phases and companies of all sizes. Both as a GCP specialist, advisor and auditor, she has conducted due diligence evaluations and participated in acquisitions.

Katarina has shaped quality and compliance functions internationally as a global pharmaceutical leader, delivering strategic initiatives and operational support in areas such as GxP quality, audits and inspections, R&D, IT, Phase I units and M&A integration. Always with a risk-based mindset. She is recognised for her rare blend of strategic vision and hands-on expertise in clinical quality and compliance which gives her a unique perspective on the challenges and opportunities across the industry. Global GCP audits, sponsor/vendor/site inspections and mock inspections across all clinical trial phases

- Health authority inspection expertise from EMA, WHO and MPA, including joint inspections with FDA
- Clinical quality and compliance strategy, inspection readiness, QMS development and risk-based oversight
- Due diligence, acquisitions, remediation, CAPA effectiveness and major quality event support
- Expert knowledge of ICH GCP, EU Clinical Trials Regulation, GDPR and digital/AI-enabled clinical trial guidance
- Designed and implemented global risk-based compliance policies, inspection strategies and oversight controls, including major health authority response support and compliance alert leadership
- Advised quality management on remediation, serious breaches, fraud/scientific misconduct investigations and GxP risk mitigation
- Languages - Swedish (native), English (full professional proficiency), French (basic professional proficiency)

Current Employment:

- Independent Consultant working on behalf of GxPAssure Limited
- Independent Principal GCP consultant at Thor Quality Consulting

Career History:

- **May 2026- Present: Thor Quality Consulting, Uppsala, SE Independent Principal GCP consultant**
  - Conduct GCP audits and mock-inspections.
  - Operational support within GCP quality.
  - Develop QMS frameworks, developing SOP by using risk-based approach.
  - Provide GCP training.
  - Assist with due diligence processes and company acquisitions.

- **Feb 2026 – May 2026: QAlliance Uppsala, SE - Senior Executive Consultant – GCP**
  - Consult pharmaceutical companies on quality and clinical trials.
  - Development of QMS, CtQ (Critical to quality factors), applying QbD (quality by design) with a risk-based approach.
  - Conduct audits and mock-inspections.
  - Training of GCP and conduct of clinical trials
  - Support with Due diligence activities and acquisitions.

- **Jun 2023 – Feb 2026: Novo Nordisk, Copenhagen, DK - Sc Vice President, Clinical Quality & Compliance**
  - Provide expert-level knowledge of relevant regulations and GxP standards and ensure company-wide compliance through proactive monitoring, communication, and implementation of regulatory requirements.
  - Set direction and defines acceptable compliance thresholds for the development of strategies and provides guidance and leadership to ensure that key compliance issues and risk mitigations are by working collaboratively across all functional and geographic boundaries.
  - Develop, provide, and conduct education programs in GCP quality and compliance including ICH GCP, inspection readiness and study-specific protocol (phase I-V).
  - Oversee integration of regulatory changes into the Quality Management System (QMS); oversee major quality events.
  - Quality partner for development of a sponsor phase 1 unit.

- **Jan 2022 – Jun 2023: Novo Nordisk, Copenhagen, DK - Vice President, Senior GCP specialist**
    - Provide expert advisement to Quality management for resolution and mitigation of GCP compliance gaps.
    - Review GCP regulations and guidance with focus on hot topic/high risk issues.
    - Develop audit plans and conduct internal, external, for cause and base-line audits.
    - Contribute to the audit certificate program by mentoring and assessing auditors.
    - Participate in regulatory inspections including mock inspections.

- **Jun 2021 – Jan 2022: Novartis, Basel, CH – Senior Compliance Advisor GCP / PV**
    - Design, development and globally implement risk-based, quality compliance related policies and oversight controls.
    - Develop the strategy and direction and review final company official responses to major HA which completely address actions being taken to correct inspectional observations.
    - Participate in regulatory inspections including mock inspections. Review and approve inspection responses and corrective actions plans to ensure consistency and appropriateness of commitments.
    - Led the Compliance Alert process across all units.
    - Review GxP regulations and guidance and made sure they were implemented correctly.

- **Apr 2019 – Jun 2021: Novartis, Basel, CH – Senior Compliance Advisor GCP**
    - Design, develop and lead implementation of compliance and inspection strategies and provide oversight governance and directions to the functional teams.
    - Ensure proper handling of complaints, potential serious breaches, fraud, and scientific misconduct investigations.
    - Identification and mitigation of potential risks.
    - Enhanced interactions with the major HAs to promote corporate-wide GxP compliance.

- **Jun 2017 – Mar 2019: Novartis, Basel, CH – Senior GCP Compliance Officer**
    - The senior-most compliance professional in the quality organisation.
    - Provide expert advice and quality leadership to all units and functions through risk-based system assessments relating to HA inspections, audits, compliance up-grade projects and ensure that remediation activities (CAPA) are undertaken and implemented including verifies of effectiveness.

- **April 2016 – Jun 2017: Medical Products Agency (Läkemedelsverket) Uppsala, SE – Expert Clinical Trials and Permissions**

- Support to all departments at Läkemedelsverket (MPA) with regulatory expertise within GCP.
- External regulatory advice.
- Development of EU Regulation and Clinical trial Directive, EMA Q&A.
- Member of CTFG (Clinical Trial Facilitation Group).

- **Jan 2014 – Mar 2016: Medical Products Agency (Läkemedelsverket) Uppsala, SE – Regulatory Assessor**
  - Assess Clinical Trial Applications, Investigational New Drugs applications and similar regulatory dossiers.
  - Evaluate clinical trial documentation, such as clinical study reports, Serious breaches etc.
  - Assess sponsor and investigator compliance.
  - Member of CTFG (Clinical Trial Facilitation Group).

- **Apr 2002 – Jan 2014: Medical Products Agency (Läkemedelsverket) Uppsala, SE – Pharmaceutical Inspector**
  - Building Läkemedelsverkets (MPA) inspection units for GCP, PV and Medical Devices including QMS.
  - Developed inspection plans and conducted inspections (site, vendor, sponsor) all over the world for EMA, MPA and WHO (GCP, PV and Medical device). Including joint inspections with FDA.
  - Conducting GCP training for the clinical trial units at the major hospitals in Sweden.
  - Close collaboration with different HAs worldwide including FDA, MHRA, Chinese FDA etc.
  - Development of EMA SOPs and guidance's and Q and A.

- **1996 – 2002: Pfizer Täby, SE - Clinical Research Associate /Clinical Research Manager**
  Oversee the operational, scientific, and compliance aspects of clinical studies within a sponsor organization.
  - Responsible for trials within the Cardiovascular area in the Nordic area.
  - Managing the monitors within the trials.
  - Designing protocol and writing Clinical study reports.
  - Application to the HAs and Ethic committees.

- **1995 – 1996: Innovex Nordic, Sweden - Clinical Research Associate**
  Ensuring that clinical trials are conducted, recorded, and reported in accordance with ICH-GCP, study protocols, and regulatory requirements
    - Monitor trials within the Cardiovascular area phase 3.
    - Arrange Investigator meetings.
    - Responsible for drug handling.

Education:

- 1994: Uppsala University, Sweden - Master of Science in Pharmacy

Member of International and National Groups

- 2022 – 2025: EFPIA support group revision of ICH GCP R3 including Annex 2
- 2019 – 2025: Intercompany Company QA group (all big pharma)
- 2014 – 2017: National implementation group for the Regulation EU No 536/2014
- 2014 – 2017: SE (supp) representative on the CTFG, Clinical Facilitation group, HMA
- 2002 – 2014: SE Representative EU GCP Inspector's Working Party, EMA
- 2005 – 2008: SE representative EU Pharmacovigilance Inspector's Working Party, EMA

Courses and Certifications

- 2025: MHRA GCP & Laboratories Symposium MHRA
- 2021/2024/2025: ICH GCP E6 (R3)
- 2024: Good Clinical Practice & Pharmacovigilance Symposium FDA, MHRA, HC
- 2024: Electronic Systems, Electronic Records, and Electronic Signatures FDA
- 2023: Considerations for Trials with Pragmatic or Decentralized Features
- 2023: Guidance on Computer Software Assurance FDA
- 2022: Data Integrity in Global Clinical Trials MHRA, FDA
- 2021: Clinical Trials Information System (CITS) EMEA
- 2020: Data Integrity in Global Clinical Trials MHRA, FDA
- 2020 Pharmacovigilance requirements for UK authorized products MHRA