

Personal Details:

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SUMMARY.

A highly motivated and dynamic quality assurance and clinical auditor who operates in a global cross functional environment with 25 years GXP experience.

Able to explore and come to pragmatic solutions ensuring compliance and strong customer orientation.

Provide compliance advice and conducts high quality risk based audits:

- Project (e.g. CRO, site audits, etc.)
- For-cause
- Systems
- PV
- Phase I
- Laboratories
- Specific compliance areas

against extremely challenging timelines, in line with the strategic and operational direction and decisions.

CAREER DETAILS.

31 Oct 2017 up to now – GCP Quality Assurance and Auditor, Independent Consultant.

In particular:

2018:

- 7 Routine CRO system audits
- 2 CRO qualifications
- 2 Distribution Sites System Audits
- 2 Pre-Inspections Audits (Italy & Poland)
- 2 days GCP Training
- 12 days site audits (Italy and Europe)
- Along the year QA support for the set-up of two Phase I Units (Oncology & Onco-haematology)