

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)

2019:

12 days Site Audits

10 days for 2 e-TMF system audits (Switzerland & Italy)

Along the year QA support for the set-up of two Phase I Units (Oncology & Onco-haematology)

2020:

2 days Site Audits

2 days CRO System Audit

3 days Phase 1 System Audit (UK All Therapeutic Areas)

2 days Remote System Audit (CRO SOPs)

4 days Remote eTMF System Audit

4 days Remote eTMF System Audit

3 days Remote CRO System Audit

3 days Remote eTMF System Audit

5 days Remote Phase 1 System Audit (Oncology)

2 days Archive Remote System Audit

4 days Remote eTMF System Audit

2 days Remote CRO System Audit

4 days Remote eTMF Audit

2 days Remote CRO System Audit

2021:

3 days remote Phase 1 System Audit

3 days QA for 2 studies amendments

2 days Remote Phase 1 Site Audit (Gastrology)

3 days Remote CRO System Audit (Gastrology)

4 days Sponsor Remediation Plan

Speaker for the Webinar: "Lo svolgimento di un audit GCP nei centri di Fase 1"

6 days Sponsor Remediation CAPA Plan

3 days QA activities for a CRO

3 days Remote Phase 1 Audit (Oncology & Onco-haematology)

2 days Remote Phase 1 Site Audit (Oncology)

6 days Sponsor Remediation CAPA Plan

1 day Site GMP Audit

2 days Site Audit Besta

10 Days Sponsor Remediation Plan

2 days Site Audit IEO

2 days Site Audit Gemelli Hospital (Oncology)

2 days Site Audit Spallanzani (Infectious Disease)

1 day Site Audit Policlinic Milan (Respiratory)

10 days Sponsor Remediation Plan

2 days Site Audit S. Matteo (Infectious Disease)

8 days Sponsor Remediation Plan

2 days Site Audit St Ander (Spain) (Respiratory)

2022:

7 days Sponsor Remediation Plan

Trainer for the SIMeF: "Corso per QA & Auditor"

1,5 days Phase I Laboratories System Audit (Humanitas)
2 days Phase I Site Audit (Humanitas)
Trainer for the SIMeF: "Corso per QA & Auditor"
8 days Sponsor Remediation Plan
2 days Site Audits Spain (Respiratory)
5 days CAPA Plans for Chinese Audits
1 day QA Phase I (Orbassano)
4 days CAPA Plans for Chinese Audits
3 days Phase I System & Site Audits (Fondazione Tettamanti)
3 days Phase I System & Site Audits (Istituto Gaslini)
2 days Phase I System & Site Audits (Tor Vergata)
6 days Sponsor Remediation Plan

2023:

2 days Phase I System Audit (Humanitas)
2 days Phase I Site Audit, (Humanitas)
2,5 days QA Phase I, Crema Hospital
Trainer for the SIMeF: "Corso per QA & Auditor"
2 days/month QA Phase I for all year, Crema Hospital
2 days CAPA Plan-Remediation Plan
Member of a Pre-inspection task Force, ongoing activities
3 days Pre-Inspection Audit, Orbassano
1 day feed-back on pre-inspection audit
2 days System Audit Phase I, Crema Hospital
2 days Pre-Inspection Audit, Rome
2 days System Audit Phase I IRCCS Policlinic Milan
6 days Pre-Inspection Audit, Orbassano
3 days Regulatory Inspection, Orbassano
2 days Site Audit Phase I IRCCS, Monza Adult
2 days Site Audit Phase I IRCCS, Policlinic Milan
2 days System Audit Phase I IRCCS, Gaslini Genova
1 day Site Audit Phase I IRCCS, Gaslini Genova
1 day Site Audit Phase I IRCCS, Monza Pediatric
2 days Site Audit Phase I ASST, Crema Hospital

2024:

1 day Phase I Microbiology System Audit IRCCS Monza
2 days System Audit CRO Hippocrates
4 days System Audit Phase I, IRCCS Policlinic Milan
2 days Pre-Inspection Audit CRO Milan
1 day Site Audit Phase I, IRCCS Monza
1 day Pharmacy Audit Phase I, IRCCS Monza
2 days System Audit, Zambon
2 days Site Audit, Humanitas Rozzano
2 days Site Audit, Policlinic Milan
3 days Site Audit, Romania

February 2014 to 31 May 2017 – Associate Director, GRAPSQA, AstraZeneca

Apr 2008 to February 2014 – CA&A Lead Advisor, Clinical Development, AstraZeneca

Achievements and Responsibilities include:

- Provision of proactive strategically focussed compliance advice mitigating risk and enhancing high clinical output across AstraZeneca compliance Areas.
- Developed and lead a new model set-up to improve Clinical Quality within Americas, West & East Europe and Asia-Pacific Regions in order to improve clinical compliance and help the Regional management to be aware about the main risk areas in their Regions and put in place mitigation tools to control the associated risk. A “Best Practice” document on how to manage subjects who are protocol violators has been developed and the related monitoring SOP has been amended in order to incorporate the “Best Practice” document.
- Provision of clear strategic and operational compliance leadership to various work-streams demonstrating clear communication and establishing a clear focus and strategic direction in extremely different cultural environments.
- Manage audit requests for for-cause audits (e.g., investigator sites, TA or region specific, systems, CROs, specific compliance areas)
- Facilitate and support regulatory authority inspections and pre-inspections for the relevant TA, region and specific compliance areas
- Plan, conduct and report audits for all therapeutic area and PV audits.
- Communication of audit findings and improvement recommendation to the auditees/audit sponsors both within AZ and externally.
- Provided compliance advice and quality updates to multiple teams at the MCs across the TAs.
- Ability to work effectively across cultural boundaries within and external to AstraZeneca
- Comprehensive knowledge of the clinical study process, AstraZeneca’s procedural documents and ICH/GCP gained from the many years spent within clinical research.
- Experienced in training/coaching/mentoring of both new and less experienced auditors personnel.
- Several experiences as chairman, trainer and speaker in “Clinical Quality” meetings:
 - “Catholic University Sacro Cuore” Faculty of Medicine in Rome. Lessons kept at the Master II level Specialization in Quality Systems for Medical Doctors (Since 2012 this was a yearly attendance)

- GIQAR Congress – Chairmen at the workshop on “Audit findings detected at Investigational Sites”. Turin, 17 May 2012
- GIQAR Congress – Chairman at the “GCP Workshop”. Bari, 23 May 2013
- Speaker at the meeting “Clinical Trials in Russia and Ukraine: Regulatory, Operational and Clinical Aspects” Society for Applied Pharmacological Sciences, Milan, 07 June 2012
- GIQAR Congress – Co-Chairman at the “GCP Workshop”. Bari, 23-25 May 2018

**Apr 1999 - Apr 2008 – Senior CQA Advisor – Quality Management, AstraZeneca
Jan 2007-Apr 2008 – Secondment in Global System Audit Group (GSA)**

Achievements and Responsibilities include:

- Reference Clinical QA person for the Europe Southern Region (Italy, Portugal, Greece and Turkey) for the years 2003-2006.
- Plan, conduct and report audits for all therapeutic area.
- Facilitate and support regulatory authority inspections and pre-inspections for the relevant TA, region and specific compliance areas.
- Communication of audit findings and improvement recommendation to the auditees/audit sponsors both within AZ and externally.
- Ability to work effectively across cultural boundaries

Sep 1994 - Apr 1999 – International Clinical Auditor, Zeneca

Achievements and Responsibilities include:

- Plan, conduct and report audits for all therapeutic area.
- Communication of audit findings and improvement recommendation to the auditees/audit sponsors.
- Ability to work effectively across cultural boundaries.

(Feb 1996 – Apr 1996 Short Secondment at Alderley Park, Manchester, UK)

Apr 1994 - Sep1994 – Therapeutic Medical Head, Zeneca, MC Italy

Achievements and Responsibilities include:

- Implementation & management of cardiovascular Phase III studies at the local level.
- Relationship and interaction with local cardiovascular KOLs.

Dec 1992 – Apr 1994 – Beta-Blockers Team Leader, ICI/Zeneca, MC Italy

Achievements and Responsibilities include:

- Implementation & management of cardiovascular beta-blockers Phase III studies at the local level.
- Relationship and interaction with local cardiovascular KOLs.
- Line management for 2 CRAs.

Dec 1990 – Dec 1992 – Senior CRA, ICI, MC Italy

May 1988 – Dec 1990 – CRA, ICI, MC Italy

Mar 1983 – May 1988 – Mario Negri Institute, Milan, Italy

Responsibilities included:

- Cardiovascular Pharmacological Research

EDUCATION

- Classical Middle School
- University of Milan, Biology BSc

OTHER QUALIFICATIONS

- Academic post doctoral qualification: Pharmacological Research
- Academic post doctoral qualification: Biotechnology

ADDITIONAL TRAINING AND FURTHER DETAILS.

- **Languages:**
 - English fluent
 - Spanish, French basic
- Co-publication of the Italian version of ICH Guidelines integrated with the Italian laws
- Active member of GIQAR (Quality Assurance Italian Group)

For the Italian Legislation:

I declare to have the minimum requirements in line with the Health Ministry Decree 31 March 2009 and related amendments 15 November 2011, to work as QA and/or Auditor.

Autorizzo il trattamento dei miei dati personali presenti nel cv ai sensi dell'articolo 13 GDPR (Regolamento UE 2016/679).

Il presente curriculum ha funzioni di autocertificazioni ai sensi del D.P.R. 445 del 28/12/2000. La sottoscritta, consapevole delle sanzioni penali previste dall'art. 76 del D.P.R. 28.12.2000, n. 445, nel caso di dichiarazioni mendaci, falsità negli atti, uso ed esibizione di atti falsi o contenenti dati non più rispondenti a verità, DICHIARA, sotto la propria responsabilità, che quanto sopra riportato corrisponde al vero.

Francesca Bucchi

GCP QA & Auditor – Independent Consultant

03/07/2023