

CURRICULUM VITAE

PERSONAL DATA

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|----------------|-------------------------|
| Name & Surname | CHIARA ALBERTONI |
| Address | --- |
| Telephone | --- |
| e-mail | --- |
| Nationality | Italian |
| Birth date | --- |

JOB EXPERIENCE

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| July 2015 – today | Compliance & Clinical Quality Assurance Consultant |
| Company Name | Freelancer |
| | Collaboration with multiple Pharma, Biotech and CRO companies |
| Company Typology/Area | Consultancy company |
| Task and Responsibilities | <ul style="list-style-type: none">• Provision of compliance and GCP regulatory expertise and support to pharma, biotech and CRO companies• Policies/SOPs/Working Instructions and Quality Manual preparation• GxP Auditing services (e.g. system audit, on-site audit, Trial Master File audit, clinical study report audit, etc.)• Preparation and support to Regulatory Inspections• Trainer on GCP and clinical trial management• Support to computerized system validation activities• Support to pharma and biotech companies for managing GDP aspects of Quality Management System (e.g. deviations, training, etc.) |
| September 2012 – May 2015 | Head of Global Quality Services & Business Excellence (formerly Quality Services International Service Unit Director) |
| Company Name and Address | THERAMetrics S.p.A. (formerly Pierrel Research Italy S.p.A.) Via Alberto Falck, 15 – Sesto San Giovanni (MI) |
| Company Typology/Area | Contract Research Organization (CRO) |
| Task and Responsibilities | <ul style="list-style-type: none">• Organization and implementation of the overall company strategy and operation targets related to the Quality Services (special focus on training, career documentation, organizational charts management, global and local policies, SOPs and other supporting documents)• Monitoring of the performance of QA/QM projects in term of associated costs and revenues• Implementation, managing and maintenance of a company specific quality system• Provision of GCP regulatory expertise and support to company staff and clients; attending meetings as Quality Service representative and GCP expert• Review of all Policies/SOPs/WIs prior to finalization and implementation• Management of contracted, non-contracted (internal) and external audits on behalf of the company or on behalf of a sponsor according to the relevant SOPs, GCP, GMP and regulatory requirements. Managing of pre-assessment visits• Reporting to the CEO on all matters within its remit, including proactive identification of issues requiring CEO/COO and Executive Board consideration.• Management of quality issues relating to the operational management of the company• Responsible for the release of new technological tools/computerized systems, duly validated and GCP compliant, in order to maximize the quality and efficiency of the different processes/activities involved in clinical trials conduction |
| March 2006 – May 2015 | Quality Assurance Manager |
| Company Name and Address | THERAMetrics S.p.A. (formerly Pierrel Research Italy S.p.A. and Hyperphar Group S.p.A.) |

Company Typology/Area
Task and Responsibilities

Via Alberto Falck, 15 – Sesto San Giovanni (MI)

Contract Research Organization (CRO)

- Definition and supervision of company training programmes
- Training courses organization
- Support to the company department responsible in evaluation of technical and professional competences of CRA (e.g. by means of co-monitoring-visits)
- Writing, review, update and management of SOPs related to clinical trial and company quality system management
- Planning and performance of system audits (including internal audit to the company departments) and study-specific audits (both in house and on-site). Support to the company management and involved functions in case of external audits; audit findings management and resolution
- Pharmacovigilance activities management
- Responsible for the release of new technological tools/computerized systems, duly validated and GCP compliant, in order to maximize the quality and efficiency of the different processes/activities involved in clinical trials conduction
- Implementation and management of Company Quality System according to ISO 9001:2000 standard
- Support to international Pierrel Research responsible regarding to QA and SOPs harmonization process

2000 – March 2006
Company Name and Address

Consultant

Pharma Qualità Europe s.r.l.

Via degli Innocenti, 2 - Figline Valdarno (FI)

Company Typology/Area

Consultancy and services in Computer System Validation and Quality Management for pharmaceutical, chemical, biomedical and medical devices industries

Task and Responsibilities

- Computer System Validation including, but not limited to, clinical databases, laboratory and ERP systems
- Validation documents issuing including, but not limited to, VPL, URS, FSP, DSP, TPL, test protocols (IQ, OQ, PQ), validation report
- Execution and support to validation activities (including risk analysis and test execution)
- Writing, review, update and management of SOPs related to GMP and GCP
- Process Mapping and Risk Management
- 21 CFR Part 11 Gap Analysis
- Planning and performance of system audits audit to computerized systems, GCP audits (in house and on-site)
- Software Supplier Selection

September 1999 – September 2000
Company Name and Address

Post-degree working experience

Bayer S.p.A.

Via Delle Groane 126 – Garbagnate Milanese (MI)

Company Typology/Area

Pharmaceutical Company – Manufacturing plant

Task and Responsibilities

Collaborating with the Responsible of the semi-finished (tablets, powers, pellets) manufacturing Department, I gained experience in:

- Writing, review, update of SOPs related to department activities
- Writing, review, update of master batch record
- Control and review of manufacturing activities through the check of the batch records filled in by operators
- Analysis of deviations: investigations, development and improvement working instructions
- Annual Batch Review

EDUCATION

March 2000

State Examination as Pharmacist

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| Institution | University of Study - Milan |
| July 1999 | Pharmaceutical Chemistry and Technology degree |
| Institution | University of Study - Milan |

SIGNIFICANT TRAININGS

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| 21 st and 22 nd October 2021 | XXIX National congress GIQAR: Quality in COVID time: changes and opportunities |
| Institution | GIQAR (Italian Group of Quality Assurance in Research) SIMeF - Milan |
| 21 st October 2021 | Pharmacovigilance in clinical trials and vigilance in clinical investigations with medical devices: common evaluation tools, the responsibility of the promoter, where to optimize the activity |
| Institution | AICRO - Milan |
| 15 th October 2021 | Clinical Research: towards new regulatory contexts - The Regulation on Clinical Trials and Medical Devices: impacts and opportunities |
| Institution | Fondazione IRCCS San Matteo and Regione Lombardia - Pavia |
| 10 th June 2021 | Conflict of interest in clinical research |
| Institution | SIMeF - Milan |
| 28 th May 2021 | The Clinical research in Italy and the European Regulation |
| Institution | AFI - Milan |
| 29 th March 2021 | Therapeutic Use of medicinal product under clinical trials (Ministerial Decree 7 September 2017) |
| Institution | SIMeF - Milan |
| 15 th January 2021 | Experience with Remote Audits (GCP, GCP/GLP Laboratories, GMP) and Virtual Inspections |
| Institution | GxP Engaged Auditing Services GmbH - Munich |
| 10 th January 2020 | Laboratory Audit in Clinical Trials |
| Institution | GxP Engaged Auditing Services GmbH - Munich |
| 11 th January 2019 | Principles of Audit Reports Writing Latest Trends in Inspections Observations |
| Institution | GxP Engaged Auditing Services GmbH - Munich |
| 09 th November 2018 | Clinical Trials with Medical Devices |
| Institution | AFI, SIMeF - Milan |
| 22 nd February 2018 | UE/EMA clinical trials documentation AIFA Inspection at clinical phase I Unit |
| Institution | SSFA – Bresso (MI) |
| 12 th January 2018 | Auditing under ICH-GCP R2 |
| Institution | GxP Engaged Auditing Services GmbH -Munich |
| 28 th September 2017 | IMP Flow |
| Institution | SSFA, AICRO – Milan |
| 20 th July 2017 | Guidance to Pharmacovigilance |
| Institution | Biogen – web training |
| 13 th January 2017 | EMA Inspection: GMP/GDP, GCP, GPvP, Quality System |
| Institution | GxP Engaged Auditing Services GmbH -Munich |
| 30 th March 2016 | Phase I Clinical Trials in Italy |
| Institution | SIF, SSFA - Rome |
| 8 th January 2016 | IT for Auditors |
| Institution | GxP Engaged Auditing Services GmbH -Munich |

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| 20 th May 2015 Institution | Inspections Preparation TheraMetrics S.p.A. - Milan |
| 10 th December 2014 Institution | GMP Annex 13 TheraMetrics S.p.A. - Milan |
| 22 nd April 2008 Institution | Meetings Management Rovatti Consulting - Milan |
| 1 st -2 nd April 2008 Institution | Public Speaking Rovatti Consulting - Milan |
| 19 th -20 th October 2006 Institution | Good Clinical Practices Advanced Course GIQAR (Italian Group of Quality Assurance in Research) - Rome |
| 2 nd December 2005 Institution | CRA Advanced Course AICRO (Italian Association of CRO) - Milan |
| 13 th 14 th October 2005 Institution | Training GCP: QA and Audit (2nd part) Sigma Tau - Pomezia |
| 6 th May 2005 Institution | Training GCP: QA and Audit Sigma Tau - Pomezia |
| 20 th -21 st November 2003 Institution | Good Clinical Practices Course GIQAR (Italian Group of Quality Assurance in Research) - Rome |
| November 2000 Institution | 2° Conference on Computer System Validation in pharmaceutical industries IQAL - Lugano, Switzerland |

Continuous training and professional refresher through the participation to national and international courses.
Last ICH-E6 GCP training on 14 May 2015.

SKILLS

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| NATIVE LANGUAGE | ITALIAN |
| OTHER LANGUAGES | ENGLISH * |
| Reading | GOOD |
| Writing | GOOD |
| Speaking | GOOD |

* Level B2 in the Council of Europe Common European Framework: final examination (FIRST exam) passed on June 2007

IT Good knowledge and use of computer

OTHER SKILLS

- Auditor certified according to Italian Ministerial Decree 15 November 2011
- Good experience as trainer
- Membership:
 - AFI – Associazione Farmaceutici Industria (Italian Pharmaceutical Association)
 - SSFA – Society for Applied Pharmacological Sciences

Being aware of the penalties in case of false statements, as per art. 76 of Italian Presidential Decree 445/2000, I declare that the information provided in the present curriculum vitae is true.

According to Reg. UE 2016/679, I authorize the processing of my personal data hereby transmitted.

Chiara Albertoni 01-DEC-21