CURRICULUM VITAE

PERSONAL DATA

Name & Surname	CHIARA ALBERTONI
Address	
Telephone	
e-mail	
Nationality	Italian
Birth date	22nd APRIL 1972

JOB EXPERIENCE

July 2015 – today	**Compliance & Clinical Quality Assurance Consultant**
Company Name	Freelancer
Company Typology/Area	Consultancy company
Task and Responsibilities	• 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
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	• 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.)

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

Company Typology/Area: Contract Research Organization (CRO)

Task and Responsibilities:

- 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 **Consultant**

Company Name and Address: 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 **Post-degree working experience**

Company Name and Address: 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

EDUCATION

March 2000	State Examination as Pharmacist
Institution	University of Study - Milan
July 1999	Pharmaceutical Chemistry and Technology degree
Institution	University of Study - Milan

SIGNIFICANT TRAININGS

22nd February 2018	UE/EMA clinical trials documentation AIFA Inspection at clinical phase I Unit
Institution	SSFA – Bresso (MI)
12th January 2018	Auditing under ICH-GCP R2
Institution	GxP Engaged Auditing Services GmbH -Munich
28th September 2017	IMP Flow
Institution	SSFA, AICRO – Milan
20th July 2017	Guidance to Pharmacovigilance
Institution	Biogen – web training
13th January 2017	EMA Inspection: GMP/GDP, GCP, GPvP, Quality System
Institution	GxP Engaged Auditing Services GmbH -Munich
30th March 2016	Phase I Clinical Trials in Italy
Institution	SIF, SSFA - Rome
8th January 2016	IT for Auditors
Institution	GxP Engaged Auditing Services GmbH -Munich
20th May 2015	Inspections Preparation
Institution	TheraMetrics S.p.A.- Milan
10th December 2014	GMP Annex 13
Institution	TheraMetrics S.p.A.- Milan
22nd April 2008	Meetings Management
Institution	Rovatti Consulting - Milan
1st-2nd April 2008	Publick Speaking
Institution	Rovatti Consulting - Milan
19th-20th October 2006	Good Clinical Practices Advanced Course
Institution	GIQAR (Italian Group of Quality Assurance in Research) - Rome
2nd December 2005	CRA Advanced Course
Institution	AICRO (Italian Association of CRO) - Milan
13th 14th October 2005	Training GCP: QA and Audit (2nd part)
Institution	Sigma Tau - Pomezia
6th May 2005	Training GCP: QA and Audit
Institution	Sigma Tau - Pomezia
20th-21st November 2003	Good Clinical Practices Course

Institution	GIQAR (Italian Group of Quality Assurance in Research) - Rome
November 2000	2° Conference on Computer System Validation in pharmaceutical industries
Institution	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

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

According to the Italian Law 196/2003, I authorize the processing of my personal data hereby transmitted.

04-MAR-2018