

PERSONAL INFORMATION

Enrico Maria Invernizzi (Update September 23, 2016)



JOB APPLIED FOR  
POSITION  
PREFERRED JOB  
STUDIES APPLIED FOR

GLP-GMP Quality Assurance

WORK EXPERIENCE

- May 2013 to Present** Merck Serono: Senior Regulatory / QA Expert
- July 2012-May 2013** Merck Serono: Site Regulatory Affair Advisor & Quality Intelligence/Non-Clinical Development GxP expertise
- May 2011-2012** Merck Serono: Global Expert Regulated NCD QA & Test Facility Head of GLP&GMP QAU
- May 2007-2011** Merck Serono: Head, Coordination GxP, QA Research & Test Facility Head of GLP&GMP QAU
- September 2006 - 2007** Serono: Test Facility Head of GLP&GMP QAU
- May 2005- 2006** Serono: QA Head of Function & Test Facility Head of GLP&GMP QAU
- March 2003 -2005** Serono: QAU Functional Matrix Leader & Test Facility Head of GLP&GMP QAU
- January 1998-2003** Serono: LCG Laboratories & Clinic Group - Pre Clinical Development QA Co-ordinator + Test Facility Head of GLP&GMP QAU
- January 1995-1998** RBM: Implementation of GMP-BQC "Vitro-Vivo" - Test Facility Head of GLP&GMP QAU
- January 1983-1995** RBM: Test Facility Head of GLP QAU
- May 1982-1983** RBM: Test Facility GLP QAU Auditor
- 1980-1982** RBM: Head of Pharmacy Unit, Toxicology Department

EDUCATION AND TRAINING

- 1974-1979** Five-year of the Chemical and Pharmaceutical Technology course, University of Turin, Italy
- 1974** Italian High School Graduation – Castellamonte (TO)

PERSONAL SKILLS

Mother tongue(s) Italian

Other language(s)

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken interaction	Spoken production	
English	B1	B1	B1	B1	B1

Levels: A1/2: Basic user - B1/2: Independent user - C1/2 Proficient user  
Common European Framework of Reference for Languages

Communication skills

- Able to communicate and create relationships with reciprocal trust;
- Ability to negotiate and influence.

Organisational / managerial skills

- Able to create common awareness of the results expected with respect to the targets set;
- Able to set clear, challenging targets and inspire enthusiasm for them to be achieved

Job-related skills	<ul style="list-style-type: none"> <li>• Knowledge of requirements, both regulatory and related to quality in the pharmaceutical industry, aimed at correctly applying GLP, GMP (<i>quality control</i>) and GCLP;</li> <li>• GLP and GMP Quality concepts, approaches and techniques;</li> <li>• Maintains and develops his own expertise by studying relevant literature and taking part in seminars, courses, etc.</li> </ul>
Computer skills	<ul style="list-style-type: none"> <li>• Knowledge of most common software packages (Word, Excel, PowerPoint, Outlook, etc.);</li> <li>• General information about the LIMS used at the site (e.g.: Provantis, Watson Lims, etc);</li> <li>• TrackWise.</li> </ul>
Other skills	Ability to identify (in synergy with key functions) the root/origin of recurrent problems and propose a solution compatible with regulations and standards, while respecting timelines and the budget.
Driving licence	Italian B

**ADDITIONAL INFORMATION**

Honours and Awards <b>April 1, 2008</b>  <b>January 2007</b>  <b>November 2003</b> <b>April 2003</b>  <b>2001</b>	BARQA CPD (Continuing Professional Development) Certification - OECD GLP (N° 1 1997), ISO 19011:2002 (Systems Auditing) SQA (RQAP) Re-Registered <b>2006-2009; 2009-2012, 2012-2015, 2015-2018</b> US SQA Registered Quality Assurance Professional in GLP (RQAP-GLP) Active Membership in US SQA BARQA - RQA (British Association of Research Quality Assurance) election to the grade of Fellow (FRQA)
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**Congresses and Lectures**

<b>2016</b>	<ul style="list-style-type: none"> <li>• 01 July 2016 - US SQA webinar - "FDA CDRH/BIMO Update"</li> <li>• 23 June, 2016- PQE Training Course "Data integrity" - Rbm</li> <li>• 18-20 May 2016 XXV GxP GIQAR Conference - Parma- Italy</li> <li>• 10 May 2016 - US SQA webinar - "FDA Guidance 218: Cell-Based Products for Animal Use"</li> <li>• 21 march 2016 - Giqar round table " Gxp &amp; Electronic Archive" Rome - Pomezia</li> <li>• 03 March 2016 - US SQA webinar "An introduction to TransCelerate: driving Quality and Efficiencies in Clinical Research" "</li> <li>• 2-3 February 2016 - Teacher at the GLP training course organized by Giqar/SSFA - Rome Università "La Sapienza"</li> </ul>
<b>2015</b>	<ul style="list-style-type: none"> <li>• 09 December 2015 "Inspection of Toxicological studies including related facilities" organized by Iris Wüthrich, Quality Consulting Wüthrich GmbH</li> <li>• 03 December 2015 US SQA webinar "Conducting Filed Audits"</li> <li>• 23 November 2015 US SQA webinar "SEND: Past, Present, and Future".</li> <li>• 23 November 2015 US SQA webinar "Common Misunderstanding Surrounding US and International GLPs".</li> <li>• 15 16 September 2015 - Teacher at the GLP training course organized by Giqar/SSFA - Rome University "La Sapienza"</li> <li>• 26 June 2015 US SQA webinar "Assessing Compliance in a Cloud Computing Environment"</li> <li>• 27-28-29 May 2015 XXIV GIQAR Conference- Napoli Italy</li> <li>• 18 February 2015, US SQA webinar: GLP Testing Facility Management in a University Setting</li> </ul>



- 19 November 2014, GIQAR – SSFA –RTC – Tavola Rotonda su: BPL – Nuova Scheda Riassuntiva delle caratteristiche del Cd Sai fini della certificazione di conformità secondo quanto stabilito dal D.L. 50 del 02/03/2015
  - 13 November 2014, US SQA webinar: Good Clinical laboratory Practices: Coloring Outside the Lines
  - 4 September, 2014 Merck Serono Biotech Regulatory CMC – webinar – Change Control Management
  - 13 August 2014 US SQA webinar "Animal Welfare Compliance (GLPSS)
  - 18-19-20 June 2014 XXIII GIQAR Conference- Ospedaletto di Pescantina (VR) Italy
  - 11 June 2014 US SQA webinar "The USA EPA Agricultural Field Trials – An Overview"
  - 10 April 2014 - Rome (Italy) - Catholic University - Second level Master on Quality System: GxP & ISO Speaker on GLP section - "Risk analysis on GLP studies"
  - 18 February 2014 US SQA webinar "The EPA Inspection Process and Discussion Points"
- 2014**
- Colletterto Giacosa (Italy) - BioIndustry Park S. Fumero - October 10, 2013 - Conference " Electronic data and Computerized System management in regulated environment"
  - Bonn (Germany) - 1<sup>st</sup> European QA Conference - 25-27 September 2013
  - Rome (Italy) - AFI (Associazione Farmaceutici Industria) - September 20, 2013 - Giornata di studio: Gestione del rischio nell'industria farmaceutica
  - 23-24 May 2013 XXII GIQAR (Italian QA Group Research) Conference - Bari -Italy
  - Turin (Italy) 10 May 2013 - University of Turin - Science and Pharmaceutical Technology - Speaker on "Quality" at the seminar entitled "Le opportunità per i giovani laureati nei diversi settori dell'industria farmaceutica"
  - Indianapolis (USA) 30 April - 2 May 2013 - 29<sup>th</sup> SQA Annual Meeting
  - Indianapolis (USA) 29 April 2013, SQA Professional development seminar "Current Trends in cGMPs.
- 2013**
- 2 April 2013 SQA webinar - "The Basic About SEND"
  - Rome (Italy) - 23 March 2013 -- Catholic University - Second level Master on Quality System: GxP & ISO Speaker on one GLP section - "Risk analysis on GLP studies"
  - Pomezia Rome (Italy) 1 March 2013 -/ - SSFA RTC - Speaker at the seminar entitled " Il laboratorio clinic: aggiornamenti regolatori e line guida"
  - Colletterto Giacosa (Italy) MerckSerono - RBM - 27 February 2013 - "Aggiornamenti Regolatori GMP e interazioni con le attività svolte in RBM" Merck Serono - Dr. Gilberto Noto Director - Head of Biotec Regulatory CMC Unit.
  - Milan (Italy) 1 February 2013 -- SSFA RTC - Speaker at the seminar entitled " Il laboratorio clinico: aggiornamenti regolatori e line guida"
  - 09<sup>th</sup> Jan 2013 MerckSerono Certificate of Auditor/Lead Auditor Qualification GLP - MerckSerono Dr. Wolfgang Seidel
- Rome (Italy), 7 December 2012 - *Italian Ministry of Health, Istituto Superiore di Sanità*- "Convegno Nazionale dei Principi di Buona Pratica di Laboratorio"- ISS Viale Regina Elena, 299 Rome
  - Colletterto Giacosa RBM (Italy) Colletterto Giacosa - MerckSerono 21 November 2012 - "GCP Documentation" - Dag Tennerus MerckSerono GCP QA
  - Colletterto Giacosa - RBM - MerckSerono 7 November, 2012 - "Multi Site Training" - Merck Serono QA - Barbara Pohl & Alessandra Grande
- 2012**
- 26 October 2012 - SQA Webinar "Good Clinical Laboratory (GCLP) Auditing
  - 1 October, 2012 - SQA October 2012 Regulatory Forum Webinar
  - RBM Merck Serono - September 20, 2012 - Attended to half day training course entitled: The Application of Good Clinical laboratory Practice (GCLP) within a GLP Laboratory - Qualogy Ltd - Tim Stiles
  - Turin (Italy), May 17-18, 2012 XXI Congresso Nazionale GIQAR
  - 24 January 2012 SQA webinar- "How to accomplish a Successful EPA GLP Inspection"
- 2011**
- Colletterto Giacosa (Italy), June 20, 2011: Bioindustry Park S. Fumero - Seminario - Speaker: "GLP Qualità in Laboratorio"
  - Rome (Italy), May 26-27, 2011: XX Congresso Nazionale GIQAR

- 2010**

  - Rome (Italy), December 21, 2010: Italian Ministry of Health, Istituto Superiore di Sanità- XV Corso - "Convegno sull'attuazione dei principi di Buona Pratica di Laboratorio. Addestramento ed aggiornamento per Ispettori e Figure professionali afferenti ai Centri di Saggio" [Via Ribotta 5, Rome]
  - Milan (Italy) - October 8, 2010: MASSA 2010 6th MS-PharmaDay University of Milan - Speaker: "Valutazione di casi di non conformità nell'impiego di metodi analitici in ambito BPL/GLP"
  - Simione (Italy), May 19-20, 2010: XIX GIQAR Congress (Italian QA National Congress)
  - Rome (Italy), February 4-5, 2010: SSFA/GIQAR, GLP Advanced Course Teacher
- 2009**

  - Brighton (UK), October 27-30, 2009: BARQA Annual Conference "Quality through the eyes of the customer"
  - Sorrento (Italy), June 4-5, 2009: XVIII Annual Congress GIQAR
  - Coleretto Giacosa (Italy), March 25, 2009: CSV LifeScience & Merck Serono - System Validation
- 2008**

  - Rome (Italy), November 4-5, 2008: NIH GLP training for HA GLP Inspectors - Speaker
  - Edinburgh (Scotland) - October 29-31, 2008 - The 2nd Global QA Conference
  - Pomezia - Rome (Italy), October 16-17, 2008 - SSFA/GIQAR, GLP Advanced Course Teacher
  - Genoa (Italy), June 12-13, 2008 - GIQAR (Italian QA National Congress)
  - Coleretto Giacosa (Italy) - Bioindustry Park del Canavese - May 15, 2008: OECD Event - MSR - Summary of Frascati OECD event
  - Frascati - Rome (Italy) ), April 11-12, 2008: OECD Event - Multilateral Symposium between Monitoring Authorities, Regulatory Authorities and Test Facilities on the implementation of the OECD Principles of Good laboratory Practice
- 2007**

  - RTC Pomezia (Rome) - Italy - November 26, 2007: Round table "Sviluppo preclinico di nuovi prodotti (prodotti biotecnologici, vaccini) nuovi saggi analitici/metodi in vitro & BPL
  - Rome (Italy) - Istituto Superiore Sanità - November 5-6, 2007: XII Corso di addestramento ed aggiornamento per Ispettori di Buona Pratica di Laboratorio (D.L.vo N° 50 del 2 marzo 2007)
  - Rome (Italy), October 25-26, 2007: SSFA/GIQAR GLP Advanced Course Teacher
  - Mondello Lido (Palermo- Italy), May 24-25, 2007: XVI Congresso Nazionale GIQAR
  - Austin (Texas, USA), 29 April - May 4, 2007: 23th SQA Annual Meeting,
  - Rome (Italy), March 15-16, 2007: SSFA/GIQAR GLP Advanced Course Teacher
  - BioIndustry Park (Coleretto Giacosa, Turin- Italy), February 21-23-26-27-28, March 7-8, 2007: Advanced Instrument Tech. applied to Biotechnology Master: Teacher on GLP Session
- 2006**

  - Cala Ginepro Orosei (NU) Italy - May 27, 2006: XV Congresso Nazionale GIQAR - Speaker with E. Lombardini on "La gestione di beni e servizi nell'ambito delle BPL"
  - Cala Ginepro Orosei (NU), Italy - May 25-26, 2006: XV Congresso Nazionale GIQAR "La Qualità al passo con i tempi: Nuove sfide per QA"
  - Phoenix (Arizona, USA), April 25-27, 2006: 22nd SQA Annual Meeting
  - Phoenix (Arizona, USA) April 24, 2006: SQA Professional Development Seminar, "GMP Regulations for GLP Auditors"

- 2005

  - Rome (Italy) - Università La Sapienza (Facoltà di Economia - Aula IX Via del Castro Laurenziano, 9), October 3, 2005: XIV Congresso Nazionale GIQAR, X Convegno BPL/BPC/BPF - Speaker on "La gestione e Valutazione del Cambiamento e della Deviazione come Indicatori della Buona Conduzione del Sistema Qualità BPL nel CdS"
  - Rome (Italy) - Università La Sapienza (Facoltà di Economia - Aula IX Via del Castro Laurenziano, 9) October 3-4, 2005: XIV Congresso Nazionale GIQAR, X Convegno BPL/BPC/BPF - "La Qualità nella Ricerca: Incontro tra Autorità di Controllo e Industria"
  - June 22, 2005: TrackWise for Deviation Management - RBM held by Serono International CQA
  - May 19, 2005: Audit Management, Supplier Quality management, Monitoring & Review Management - RBM held by Serono International CQA
  - May 18, 2005: Deviation handling, Change Control Management, Equipment Maintenance & Calibration, Validation Management - RBM held by Serono International CQA
  - Orlando (Florida, USA), February 22-24, 2005: 1st Global QA Conference and 21st SQA Annual Meeting - Speaker on "MultiSite Toxicology Studies - The Sponsor Point of View"
  - Orlando (Florida USA), February 21, 2005: SQA Professional Development Seminar, "Compliance Requirements for Equipment and Instrumentation in GLP Studies"
  - Orlando (Florida USA), February 20, 2005: SQA Professional Development Seminar, "Biotechnology For Rookies"
  - Orlando (Florida USA), February 20, 2005: SQA Professional Development Seminar, "Auditing Biotechnology Techniques and Data"
- 2004

  - Sorrento (Italy), May 27-28, 2004: XIII Congresso Nazionale GIQAR
  - Dublin (Ireland), May 5-7, 2004: BARQA 2004 International Conference - A New Era Dawn
  - Reno (Nevada, USA), April 27-29, 2004: SQA 20th Anniversary Meeting
  - Reno (Nevada, USA), April 26, 2004: SQA Professional Development Seminar - Advanced Concepts in Computer Validation
- 2003

  - Divonne (France) 2-3 December 2003: Serono International SA - QA Seminar
  - VIII Course of "Training and up to date for GLP Inspector - Organized by "Istituto Superiore di Sanità" Italian Ministry of Health. Rome, - November 10, 11 and 17, 2003
  - November 26, 2003: US SQA Registered Quality Assurance Professional in GLP (RQAP-GLP)
  - Washington DC (USA), October 14-16, 2003: SQA 19th Annual Meeting
  - Washington DC (USA), October 13, 2003: SQA Professional Development Seminar "New horizons in the Life of a GLP auditor"
  - Sestri Levante (Italy), May 15-16, 2003: GIQAR - XII National Congress
  - Sestri Levante (Italy), May 14, 2003: GIQAR - XII National Congress - Teacher in "GLP Basic Course"
- 2002

  - Manchester (UK), November 6-8, 2002: BARQA Annual meeting
  - Rome (Italy), June 12, 2002: SSFA/GIQAR Round table - OECD Monograph no. 13. "The application of the OECD principles of GLP to the organization and management of multisite studies" Working group
  - Alghero (Italy), May 20-21, 2002: GIQAR - XI National Congress, Congress moderator
- 2001

  - Rome (Italy), May 14-15, 2001: ISS-Istituto Superiore di Sanità/Italian Ministry of Health - GLP Congress "I nuovi principi di Buona Pratica di Laboratorio, priorità, problemi, prospettive"; Speaker on "Different Quality System Compatibility"
- 2000

  - Rome (Italy), November 13, 2000: Course of "Training and up to date for GLP Inspector - General part" Organized by "Istituto Superiore di Sanità" Italian Ministry of Health
  - Milan (Italy), October 10, 2000: AFI (Associazione Farmaceutici Industria) - Quality Assurance Study Course- Modulo VIII - GLP on Pre clinic Research Quality Assurance - Speaker on: The QA and FDA Inspection
  - Milan (Italy), June 8-9, 2000: Milan University- Faculty of Pharmacy- Tox Postgraduate school- GLP & GMP Course Teacher
  - Giardini Naxos (Messina-Italy), May 18-19, 2000: GIQAR - IX National Congress, Speaker on: "Suggestions to make preparations for a regulatory inspection"
- 1999

  - Turin (Italy), July 9, 1999: Turin University - Biology Diploma - GLP&GMP Course Teacher Course of "Training and up to date for GLP Inspector- General part" organized by "Istituto Superiore di Sanità" Italian Ministry of Health
  - Rome (Italy), December 2, 1999: Lecture on "Millennium bug problem and management tools within CRO environment"

- 1998

  - Rome (Italy), November 16, 1998: Course of "Training and up to date for GLP Inspector - General part" Organized by "Istituto Superiore di Sanità" Italian Ministry of Health
  - Grottaferrata (Rome, Italy), June 17-19, 1998: National Congress of Italian Q.A., GIQAR
- 1997

  - Napoli (Italy), November 13-14, 1997: National Congress "GIQAR" (Q.A. Italian group of research) Presentation of "The use of Quality Indicators as Q.A. management tool"
  - Rome (Italy), November 5-6, 1997: Course of "Training and up to date for GLP Inspector" Organized by "Istituto Superiore di Sanità" - Italian Ministry of Health
  - Bari (Italy), May 24-30, 1997: GMP "Quality Issue Conference III (QIC III)" Organized by "Ares Serono Group", Corporate Quality Assurance & Regulatory Compliance, Geneva
- 1996

  - Florence (Italy), June 6-7, 1996: 4th National Meeting of Quality Assurance Italian Group of Research (GIQAR)
  - Rome (Italy), October 30-31, 1996: Conference on "Principles of Good Laboratory Practices and Conduction of Inspection Activities" Organized by Istituto Superiore di Sanità - Italian Ministry of Health - Presentation of "CRO point of view in inspection matter"
- 1995

  - Glasgow (UK), May 10-12, 1995: 10th International Congress Compliance & Computers Regulatory Needs and Quality Expectations, Organized by BARQA Computing Committee
- 1994

  - Rome (Italy), June 9-10, 1994: 4th National Meeting of Quality Assurance Italian Group of Research (GIQAR)
  - Barcelona Sants (Spain), May 4-6, 1994: 9th International Congress of Research Quality Assurance organized by BARQA in association with SEGCIB
  - Loranze - Turin (Italy), March 7-12, 1994: Seminar on Fundamentals of Management - Organized by the Ares Serono Group Training Centre Tuition: Prof. Philip Law and Laura Cousins from London Business School - London
- 1993

  - Milan (Italy), November 22, 1993: Course on Preclinical Studies Organized by Gruppo Scientifico Italiano Studi e Ricerche
  - Milan (Italy), November 12, 1993: Role of Q.A. in Clinical Trial Organized by GIQAR (Italy)
- 1992

  - Rome (Italy), June 11-12, 1992: 3rd National Meeting of Quality Assurance Italian Group of Research (G.I.Q.A.R.)
  - London (UK), April 22-24, 1992: 8th International Congress on Good Laboratory and Clinical Practices Organized by British Association of Research Quality Assurance - Formerly QAG (UK)
  - Nemi (Rome, Italy), June 6-7 1992: 2th International Meeting of Quality Assurance Italian Group of Research (G.I.Q.A.R.) Presentation on Statistical Computerized control of data in compliance with the rule UNI 4842
- 1990

  - Cannes (France), May 2-4, 1990: 7th International Congress on Good Laboratory Practice Organized by QAG (UK) and SoFaQ
- 1989

  - Turin (Italy), May 17, 1989: 'The Certification in the Pharmaceutical Industry'. Meeting of the AFI, CNR and UNI
  - Rome (Italy), May 19, 1989: "The Good Laboratory Practice" Meeting of the SSFA/GIQAR, SISF and Faminustria
  - Rome (Italy), March 14-15, 1989: International Centre for Health and Environmental Education Seminar: Introduction to Computer System Validation
- 1988

  - Stratford-Upon-Avon (UK), April 17-20, 1988: 6th International Congress on Good Laboratory Practice, organized by the U.K. Quality Assurance Group
- 1987

  - Milan (Italy), October 9, 1987: "Quality Assurance in the Italian Pharmaceutical Industry" Meeting of the Society for Applied Pharmacological Sciences and Industrial Pharmaceutical Society
  - Milan (Italy), May 25, 1987: Overview of GLP implementation in Japan presented by Dr. Masani Kitano. Meeting of the Society for applied Pharmacological Sciences
  - Milan (Italy), February 19, 1987: Responsibility of Management and of Quality Assurance under the GLPs presented by Dr. P. Lepore. Meeting of the Society for Applied Pharmacological Sciences

- 1986**
  - Frankfurt (W. Germany), May 11-13, 1986: 5th International Meeting on Good Laboratory Practice organized by the U.K. Quality Assurance Group
  - Ivrea (Italy), 1986: RBM Meetings 1 - Receptor in Pharmacology
  - Ivrea (Italy), 1986: RBM Meetings 2 - Topics in Reproductive Toxicology
- 1985**
  - Den Haag (the Netherlands), December 16-18, 1985: Centre for professional advancement - Course on Good Laboratory Practices
  - Cambridge (UK), April 1-3, 1985: 4th International Meeting on Good Laboratory Practice organized by the U.K. Quality Assurance Group University of Cambridge
- 1984**
  - St. Vincent (Aosta) Italy: Pharmacology and Experimental Therapy Institute 12th updating Course on Toxicology University of Torino

**Memberships**

- 1985** Italian Group of Research Quality Assurance (GIQAR)
- 1985** Italian Society of Applied Pharmacological Sciences (SSFA)
- 1987** British Association of Research Quality Assurance (former BARQA - RQA) - **"Fellow"** (FRQA)
- 1999** U.S. Society of Quality Assurance - Active Member - (SQA) **RQAP-GLP** (Registered Quality Assurance Professional in GLP)
- 2013** U.S. IQ Consortium GLP QA LG - International Consortium for Innovation and Quality in Pharmaceutical Development
- 2013** GxP Solution - Italian Scientific Group - GLP Expert

**ANNEXES**

Replace with list of documents annexed to your CV. Examples:

- copies of degrees and qualifications;
- testimonial of employment or work placement;
- publications or research.

Il sottoscritto, acquisita l'informativa di cui all'art. 13 Decreto Legislativo 196/03 con l'invio del proprio CV presta il proprio consenso, ai sensi degli art. 23 e 26 del decreto stesso, al trattamento dei dati personali, anche sensibili, che ha ritenuto opportuno indicare nel CV.

