# Curriculum Vitae

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## WORK EXPERIENCE

Jan 2024 - present — **Quality Assurance Consultant**
Stavares Consulting Unipessoal Lda, Porto, Portugal

2018 - present — **Tutor at RQA GCP Auditing course**

Feb 2023 – Oct 2023 — **Director, Quality Assurance Research**
Bial - Portela CA, SA, Porto, Portugal
Management of an audit programme, conduct of GCP, GCLP, GLP and GVP audits, management of a global QA programme including Deviations, Change Control, SOPs and training.

**Audit Experience:**

- GCLP Audits: central laboratories
- GLP Audits: animal welfare, GLP vendors
- GCP Audits: site audits
- GVP Audits: distributors, partners, documents

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| Jan 2011 – Feb 2023 | **Head of Quality Assurance – Research**<br>Bial - Portela CA, SA, Porto, Portugal<br>Management of an extensive audit programme of up to 250 audits a year, hosting inspections, inspection preparation, conduct of GCP, GCLP, GLP and GVP audits, management of a global QA programme including Deviations, Change Control, SOPs and training.<br><br>**Audit Experience (On-site and Remote):**<br>• GCLP Audits: central laboratories<br>• GLP Audits: animal welfare, GLP vendors<br>• GCP Audits: investigator site audits, phase I units, system audits, vendor audits, for cause audits, inspection preparation and hosting inspections<br>• GVP audits: system, vendors, distributors, partners, documents |
| Jan 2006 – Dec 2010 | **Quality Assurance Technician**<br>Bial - Portela CA, SA, Porto, Portugal<br>Management of an audit programme, hosting inspections, inspection preparation, conduct of GCP, GCLP, GLP and GVP audits, management of a global QA programme including Deviations, Change Control, SOPs and training.<br><br>**Audit Experience:**<br>• GCLP Audits: bioanalytical laboratories, internal QAM, central laboratories<br>• GLP Audits: bioanalytical laboratories, animal welfare, GLP vendors<br>• GCP Audits: investigator site audits, phase I units, system audits, vendor audits<br>• Due diligence |
| Mar 2002 – Dec 2005 | **Clinical Research and Safety Manager Technician (and GLP quality assurance technician)**<br>Bial - Portela CA, SA, Porto, Portugal<br>Implementation of GLP quality system in a laboratory and performance of quality assurance activities (study, process and facility audits), hosting and preparation of GCLP inspections, clinical management activities |

## AUDITING AND QUALITY CONSULTANCY EXPERIENCE:

GCP:

- Approximately 23 Investigator site audits (as lead of Routine Phase II, III, IV studies), 24 Inspection Readiness (details below), 7 For Cause
- Approximately 31 vendors/suppliers: 13 Clinical Unit/Phase I-IIa, 7 Full-Service CRO, 2 PK CRO, 7 Data Management CRO, and 2 Archive
- Approximately 16 document audits: 4 Protocol, 1 CSR, 1 ICF, 3 IB, 4 eTMF, 3 ISF

- Approximately 2 system audits
- Approximately 3 due diligence audits

- Hosting 12 GCP Inspections:
    - Infarmed GCP Phase I Unit Inspection, Portugal (2006)- on site
    - Infarmed GCP site Inspection, Portugal (2010)- on site
    - EMA GCP site Inspections, Czech Republic (2011) - on site
    - FDA, GCP Site Inspection, Brazil (2013) - on site
    - FDA GCP Sponsor Inspection USA (2013) - on site
    - 2 EMA, GCP Site Inspections, India (2015) - on site
    - FDA, GCP Site Inspections, Poland, South Korea, Portugal (2019) - on site
    - FDA, GCP CRO Inspection, France (2019) - on site
    - FDA, GCP Bioanalytical Inspection, Switzerland (2019) - on site
    - 2 MHRA, GCP sponsor inspection, Portugal (2020, 2023) - remote
- Preparation for 27 Clinical Inspections
    - 1 Infarmed GCP Phase I Unit Inspection, Portugal (2006)- on site
    - 1 sponsor inspection (2010) on site US
    - 2 EMA, GCP Site Inspections, India (2015)- on site
    - 14 FDA GCP site Inspections – Brazil, Argentina, Hungary, Czech Republic, India, South Korea (2013) – 4 on site, 10 remotely
    - 6 FDA GCP site Inspections – Poland, Portugal, South Korea, South Africa, Ukraine, France (2019) – 3 on site, 3 remotely
    - 2 sponsor inspection on site (2018)
    - 1 FDA GCP Phase I Unit Inspection –France (2019) – on site
- Meeting with Authority:
    - Attendance at an FDA meeting as Quality Assurance manager (2010, 2011)

- Quality Management consultancy: inspection readiness (GCP, GVP, GCLP, GLP), quality management (GCP, GVP, GCLP, GLP), SOP Writing (GCP, GVP, GCLP, GLP), GxP Training (GCP, GVP, GCLP, GLP)

## GVP:

- Approximately 15 audits: 8 Affiliates, 7 Partner, 5 Vendors, 2 Pharmacovigilance system, 7 Distributors
- Hosting of 4 Pharmacovigilance Inspections:
    - EMA/Infarmed, Pharmacovigilance System Inspection, Portugal (2011, 2016, 2020) – 2 onsite, 1 remotely
    - AEMPS, Pharmacovigilance System Inspection, Spain (2018) – on site
- Preparation of 4 Pharmacovigilance Inspections:
    - 3 EMA/Infarmed, Pharmacovigilance System Inspection, Portugal (2011, 2016, 2020) - on site
    - 1 AEMPS, Pharmacovigilance System Inspection, Spain (2018) – on site

## GLP/GCLP:

- Approximately 373 audits: 326 internal bioanalytical laboratory audits (independent audits of the company's laboratory, including study-specific audits and process audits; approximately 20% GLP and 80% GCLP focus); 9 external bioanalytical laboratories, 6 central laboratories for clinical trials, 12 Inspection Preparations, 7 Vendor, 17 Preclinical CROs, 2 non regulated
- Hosting 12 GCLP Inspections (on site):
    - Infarmed, GLP Bioanalytical Laboratory Inspection, Portugal (2002, 2003, 2005, 2006, 2007, 2008, 2009, 2010,2011, 2012, 2013, 2016)

- 12 Inspection preparations for:
    - Infarmed, GLP Bioanalytical Laboratory Inspection, Portugal (2002, 2003, 2005, 2006, 2007, 2008, 2009, 2010,2011, 2012, 2013, 2016) – on site

GMP:

- Approximately 3 audits: 2 Warehouses and 1 system audit of IMP management system

QMS:

- Management of more than 2500 GCP, GVP, GCLP, GLP and GMP audits between 2002 and 2023

| Area | Number of audits managed between 2002 and 2023 |
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| GLP and GCLP | 694 |
| GCP | 1695 |
| GVP | 260 |
| GMP | 8 |

- Quality Management consultancy GCP, GVP, GCLP, GLP
- SOP and Policy Development GCP, GVP, GCLP, GLP
- GCP, GVP, GCLP, GLP Compliance
- Training Materials – Investigator's Meetings, Annual GCP, GVP, GCLP, GLP refresher training

Countries:

Portugal, Spain, UK, France, Germany, Netherlands, Poland, Hungary, Serbia, Ukraine, Latvia, Romania, Czech Republic, Switzerland, Scotland, Lithuania, Albania, Cyprus, Malta, Belgium, Ireland, Russia, Panama, Japan, South Korea, Taiwan, Singapore, India, Mexico, Brazil, Argentina, Canada, US, Chile, Mozambique

Audit standards:

- ICH-GCP; c-GLP; EU regulatory requirements for Clinical Trials / Pharmacovigilance / Medical Information]; FDA CFR part 11; Portuguese National regulatory requirements; EN ISO 9001:2015, NP 4457/2021

## EDUCATION

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| Jan 2024- ongoing | Executive Master in Sustainability Management, Porto Business School |
| Sep 2009 – July 2011 | Especialização em Evidência e Decisão em Saúde, Faculty of Medicine, University of Porto, Portugal, 14/20 |
| Sep 2000 – July 2002 | European Master of Analytical Chemistry, Faculty of Pharmacy, University of Porto, Portugal, Very Good, MSc |
| Sep 1993 – July 1999 | Degree in Pharmaceutical Sciences, Faculty of Pharmacy, University of Porto, Portugal, 13/20, BSc |

## PROFESSIONAL TRAINING/CERTIFICATION

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|---|---|
| 2024 | Research Quality Assurance Conference, 2024, Brighton |
| 2024 | Pharmacovigilance Training, Unidade de Farmacovigilância Porto |
| 2024 | 3rd National Meeting on Clinical Research and Biomedical Innovation, Portugal |
| 2024 | Seminário sobre as Boas Práticas na Gestão dos Sistemas de Gestão, XZ Consultores, Portugal |
| 2024 | Contract Management in Clinical Trials, AICIB, Portugal |
| 2024 | Quality management and Internal Audits at Certfom, Portugal |
| 2023 | Good Pharmacovigilance annual Training, at BIAL, Porto, Portugal |
| 2023 | Good Clinical Laboratory Practices at BIAL, Porto, Portugal |
| 2023 | Changes on ICH-E6 R2 at BIAL, Porto, Portugal |
| 2022 | GCP Annual training at S-Cubed, Porto, Portugal |
| 2022 | Quality in Preclinical Activities at BIAL, Porto, Portugal |
| 2022 | EU-CTR 536/2014, Porto at BIAL, Portugal |
| 2021 | GCP Annual training at S-Cubed, Porto, Portugal |
| 2021 | GLP and GCP for Analytical Laboratories HQE, Porto, Portugal |
| 2021 | PV annual training by QA Research at Yabulu, Porto, Portugal |
| 2021 | Pharmacovigilance – Actual Challenges at Apifarma, Lisbon, Portugal |
| 2021 | GxP Auditors Training: Writing and Review of BIAL Audit Reports at S-Cubed, Porto, Portugal |
| 2020 | Annual Pharmacovigilance Training at BIAL, Porto, Portugal |
| 2020 | GLP and GCLP Refresher Training at Chapman Ltd, Porto, Portugal |
| 2020 | GCP Annual training at Chapman Ltd, Porto, Portugal |
| 2019 | GCP Annual training at S-Cubed, Porto, Portugal |
| 2019 | Annual Pharmacovigilance Training at Propharma group, Porto, Portugal |
| 2018 | GLP and GCLP Refresher and QMS in non-regulatory Research at Chapman Ltd, Porto, Portugal |
| 2018 | Regulatory Update 2018- MHRA GLP/GCP Symposium February 2018 Feedback at AF International Consultancy, Porto, Portugal |
| 2018 | GCP Annual training at S-Cubed, Porto, Portugal |
| 2017 | GLP and GCLP Refresher and QMS in non-regulatory Research at Chapman Ltd, Porto, Portugal |
| 2017 | GCP Annual training at BIAL, Porto, Portugal |
| 2017 | What to expect from ICH E6 R2 Addendum and its implication at BQA, Porto, Portugal |
| 2017 | Participation in practical Task about Risk management at BIAL, Porto, Portugal |
| 2017 | Understand the overall importance of IB and where it fits in the Research Process; Feedback from IB audits and lessons learned; Regulatory Expectations for multiple IBs and reference safety information at BQA, Porto, Portugal |

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| 2017 | NP 4457:2007 at Iberogestão, Porto, Portugal |
| 2016 | GCP Training: Overview of ICH GCP; New European Clinical Trials |
| 2016 | Regulation - The "Clinical Trials Regulation" No 536/2014; Regulatory Inspections (Investigator sites); EMA reflection paper for laboratories that analyze/evaluate clinical trial samples at S-Cubed, Porto, Portugal |
| 2016 | What to expect during an inspection; Participation in Inspection Interviews: guidance on responding to questions and behavior during the interview; Clarification of how the mock inspection interviews that take place at Xendo, Porto, Portugal |
| 2016 | GMP training at BIAL: Qualified Person and Batch Release, Deviations and Complaints, process and Cleaning validation, Porto, Portugal |
| 2016 | IMP Production Annex 13 at Bial, Porto, Portugal |
| 2016 | Launch of the National Registry of Clinical Studies (RNEC) at Infarmed, Lisbon, Portugal |
| 2016 | NP4457: Management of Research, Development and Innovation (RDI) |
| 2015 | NP EN ISO 19011:2012, Boas Práticas de Auditorias (Rui Botelho) at BIAL, Porto, Portugal |
| 2014 | Me & BIAL - Leadership Development, Interpersonal and Relational Skills at Porto Business School, Porto, Portugal |
| 2013 | Good Pharmacovigilance Practice (GVP) Annual Training at Bial, Porto, Portugal |
| 2013 | Good Laboratory Practice (GLP) Refresher Training at OQC, Porto, Portugal |
| 2013 | Good Manufacturing Practice (GMP) Annual Training at Bial, Porto, Portugal |
| 2012 | New Guidelines on Good Pharmacovigilance Practices at Bial, Porto, Portugal |
| 2012 | Presentation on FDA inspection methodology and likely FDA focal points at Sunovion, US |
| 2012 | Observation Investigation: Post Marketing Studies, Apifarma, Lisbon Portugal |
| 2012 | GLP Training; Good Clinical Laboratory Practice Training at S-Cubed, Porto, Portugal |
| 2012 | Good Clinical Laboratory Practice Training at S-Cubed, Porto, Portugal |
| 2012 | GLP Pratice Training for Study Directors and Principal Investigators at S-Cubed, Porto, Portugal |
| 2012 | GCP Refresher: The Core principles of Good Clinical Practice; The Regulatory Landscape; Maximising the use of internal expertise BQA, Porto, Portugal |
| 2011 | New Guidelines on Good Pharmacovigilance Practices at BIAL, Porto, Portugal |
| 2011 | GCP Update Training at J3i Quality, Porto, Portugal |
| 2011 | GCP Medical Affairs workshop J3i Quality, Porto, Portugal |
| 2011 | GLP Annual Training at OQC, Porto, Portugal |
| 2011 | GMP Annual Training at Growing Within, Porto, Portugal |

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| 2011 | Pharmacovigilance New European, FDA AND ARS PV Legislation, Bial, Porto, Portugal |
| 2010 | Good Laboratory Practice (GPL) Training for Staff New to GPL and Refresher Training for Existing Staff: Overview of current GPL findings from Regulatory Authorities at OQC, Porto, Portugal |
| 2010 | GMP Training at TÜV Rheinland, Porto, Portugal |
| 2009 | ISO9001:2008: Principal Changes to the previous version ISO9001:2000 at Bial, Porto, Portugal |
| 2009 | Maximizing your quality system for PV at Vigilex, Porto, Portugal |
| 2009 | Preparation for an FDA Inspection at Galenisys - Steve Biddulph, Porto, Portugal |
| 2009 | Serious GCP Breach Training at OQC, Porto, Portugal |
| 2009 | Compliance in Laboratories that analyze GCP samples including GLP Refresher Training at OQC, Porto, Portugal |
| 2009 | Good Manufacturing Practices Training, TUV, Porto, Portugal |
| 2009 | Getting excited about Volume 9A |
| 2009 | Pharmacovigilance Risk Management, Yabulu, Lisbon, Portugal |
| 2009 | Maximizing your quality system for PV, Vigilex, Porto, Portugal |
| 2008 | Training in Volume 9A of the Rules Governing Medicinal Products in the European Union - Guidelines on Pharmacovigilance for Medicinal Products for Human Use at NDA Regulatory Science, Porto, Portugal |
| 2008 | Good Clinical Practices at BARQA, UK |
| 2008 | Preparing for audits and inspections in Pharmacovigilance at Vigilex, Porto, Portugal |
| 2007 | Good Laboratory Practice Training at OQC, Porto, Portugal |
| 2007 | Volume 9A Practical Implications at Vigilex, Porto, Portugal |
| 2007 | NP 4457: Gestão da Investigação, Desenvolvimento e Inovação at Iberogestão, Porto, Portugal |
| 2007 | Systems Audit at BARQA, UK |
| 2007 | GCP Training at OQC, Porto, Portugal |
| 2006 | GMP Auditing Training Course at Bial, Porto, Portugal |
| 2006 | Good Clinical Practices Auditing: Principles and Practice at BARQA, UK |
| 2005 | Clinical Project Management at Barnett International, Belgium |
| 2004 | Good Laboratory Practice Training at Qualitas, Porto, Portugal |
| 2004 | Lei nº 46/2004 de 19 Agosto at Bial, Porto, Portugal |
| 2004 | Data Handling and data Management Processes at Kingston University, UK |
| 2004 | Application of IT in CDM at Kingston University, UK |
| 2004 | Data Handling, data Management Processes at Kingston University, UK |
| 2003 | Good Laboratory Practice Training at Relacre, Porto, Portugal |
| 2003 | ISO 9001:2000 - Gestão por Processos at IEP, Porto, Portugal |
| 2003 | Directiva 2001/20/EC at Bial, Porto, Portugal |
| 2003 | Intermediate Clinical Data Management at Association of Clinical Data Management |

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| 2003 | Exploring Statistics using the Analyst Application at SASINST Software, Lda, Lisbon, portugal |
| 2003 | SAS Programming I, Essentials at SASINST Software, Lda, Lisbon, Portugal |
| 2003 | GCP & Regulatory Process at Kingston University, UK |
| 2002 | Quality Audits at PSI, Porto, Portugal |
| 2002 | Drug Development & Clinical Methodology at Kingston University, UK |
| 2002 | Good Laboratory Practices at PSI, Porto, Portugal |
| 2002 | Pharmacovigilance System at BIAL, Porto, Portugal |
| 2002 | Internal Training in Evaluation, Development and Implementation of ISO 9001: 2000 |
| 2000 | Training for Trainer at Cequal, Porto, Portugal |
| 2000 | Quality Auditors Training at AEP, Porto, Portugal |

## LANGUAGES

Native: Portuguese
Fluent: English
Understand: Spanish

## MEMBERSHIPS

RQA
Pharmaceutical Association

## PUBLICATIONS OR PRESENTATIONS

| | |
|---|---|
| 2005 | Maia, M. Vaz-da-Silva, A. Falcão, E. Soares, S. Tavares, P. Silveira, L. Almeida, P. Soares-da-Silva, 2005, “Effect of Eslicarbazepine Acetate (BIA 2-093) on the steady-state Pharmacokinetics of Digoxin in Healthy Subjects”, Epilepsia 2005; 46 (Suppl.6): 283 |
| 2005 | T. Nunes, A. Falcão, L. Almeida, R. Lima, S. Tavares, C. Neta, C. Fontes-Ribeiro, T. Macedo, P. Soares-da-Silva, 2005, “Eslicarbazepine Acetate (BIA 2-093): Relative Bioavailability and Bioequivalence of 50 mg/mL Oral Suspension and 200mg and 800mg Tablet Formulation”, Epilepsia 2005; 46 (Suppl.6): 121 |
| 2005 | T. Nunes, A. Falcão, L. Almeida, R. Lima, S. Tavares, C. Neta, C. Fontes-Ribeiro, T. Macedo, P. Soares-da-Silva, 2005, “Eslicarbazepine Acetate (BIA 2-093): Relative Bioavailability and Bioequivalence of 50 mg/mL Oral Suspension and 200mg and 800mg Tablet Formulation”, Epilepsia 2005,; 46 (Suppl.6): 121 |

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| 2005 | Manuel Vaz-da-Silva, Ana I. Loureiro, Teresa Nunes, Joana Maia, Susana Tavares, Amilcar Falcão, Pedro Silveira, Luis Almeida and Patricio Soares-da-Silva. Bioavailability and Bioequivalence of two Enteric-Coated Formulations of omeprazol in Fasting and Fed Conditions. Clin Drug Investigation 2005;25(6):1 |
| 2001 | Susana Tavares, Agostinho Almeida e José L.C.Lima , 2001, " A amostragem in situ com microcolunas de Metalfix ChelaminaÒ na determinação de elementos vestigiários em águas naturais por ICP-MS (método Epa 200.8)" , XV Encontro Galego português de Química , Corunha, P4-64 |
| 2001 | Susana Tavares, Agostinho Almeida e José L.C.Lima, 2001, "Trace and Ultra-trace element analysis of Portuguese bottled mineral water using ICP-MS EPA method 200.8" , II Meeting of Requimte, Monte da Caparica, PO36 |

## VOLUNTARY WORK

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| Jan 2020-Ongoing | President of Portuguese Celiac Association |
| Sep 2022-Ongoing | Vice -Chair of the Board of Association of European Celiac Associations |