



## Curriculum Vitae

Personal information **Tiago Vistulo De Abreu**

### Work experience

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1. Employer: INFARMED, I.P. - The Portuguese Authority of Medicines and Health Products
  - Start date: 05, 2001
  - End date: Present
  - Position: Quality Assessor of Medicinal Products for Human Use
  - Activities:
    - Assessment of the chemical and pharmaceutical documentation of synthetic active substances and medicinal products from different routes of administration and dosage forms (oral, parenteral, ophthalmic, auricular, nasal, inhalation and cutaneous), different technologies (using traditional and QbD approaches), different procedures (National, Decentralised, Centralised, Scientific Advices, CEP, ASMF) at different phases of the life-cycle of the products (including, clinical trials, marketing authorisations, variations, renewals, quality defects and batch recalls).
    - Training of other quality assessors from INFARMED, I.P. and other regulatory authorities.
    - Participation in Quality Working Party (QWP) meetings as observer (2007-2019), alternate member (2020-June 2023); member (July 2023-current).
    - Participation in the Portuguese Medicines Evaluation Committee.
    - Participation in the Sub-Committee of Quality Experts of INFARMED.
  - Country: Portugal and EMA (United Kingdom / Netherlands)
2. Employer: INFARMED, I.P. - The Portuguese Authority of Medicines and Health Products
  - Start date: 02, 2000
  - End date: 04, 2001
  - Position: Pharmaceutical Technician
  - Activities:
    - Quality control at INFARMED's Laboratory Department of Biopharmacy and Pharmaceutical Technology.
    - Operation of new automated dissolution and disintegration testers for routine analysis of tablets and capsules.
    - Comparative studies on the dissolution and disintegration profiles of marketed medicinal products.
    - Selection and purchasing of chemical reference standard and lab material.
  - Country: Portugal
3. Employer: SIDEFARMA (Portugal), ASTA MEDICA Group
  - Start date: 07, 1996
  - End date: 07, 1998
  - Position: Pharmaceutical Technician
  - Activities:
    - Quality Control of Medicines in a pharmaceutical company specialized in the manufacture of solid, semi-solid and liquid dosage forms.
    - Operation of several QC equipments.
    - Training of analysts.
    - Implementation of ISO 9002 Quality Standards.
    - Writing of Standard Operating Procedures (SOPs).
    - Definition and Implementation of calibration plans.
    - Management of reference and working standards and reagents.
    - Decision about the quality level of raw materials, packaging materials and semi-finished products.
    - Participation in several courses provided by the company.
  - Country: Portugal

### Education and training

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#### Education and Traineeships

1. Subject: Master of Science in Pharmaceutical Analysis
  - Start date: 09, 1998
  - End date: 09, 1999
  - Qualification: MSc
  - Organisation: University of Strathclyde, UK. Research project conducted at EDQM Laboratory, Council of Europe, Strasbourg, France.
  - Country: United Kingdom and France.
  - Subjects/Skills: core lectures and laboratory instruction on method validation, statistical analysis, chemical analysis, quantitative spectrophotometry, chromatography and electrophoresis, radiopharmaceuticals, experimental design & optimisation, structural elucidation, preformulation and formulation studies, sterile product manufacture, drug instability, quality control of biotechnology products, quality assurance and management.
  - Thesis: "Capillary Electrophoresis of Aminoglycoside Antibiotics".

## 2. Subject: ERASMUS Scholar

- Start date: 09, 1995
- End date: 01, 1996
- Qualification: Traineeship at Hospital Pharmacy - ERASMUS Programme
- Organisation: Royal Danish School of Pharmacy and Danish State University Hospital
- Country: Denmark
- Subjects/Skills: clinical project undertook with relation to the pharmacokinetics of cyclosporine in patients with heart transplant.

## 3. Subject: Traineeship at Pfizer

- Start date: 05, 1995
- End date: 08, 1995
- Qualification: Traineeship at Pharmaceutical Industry
- Organisation: Apprenticeship in production, packaging areas as well as in the quality control laboratory.
- Country: Portugal

## 3. Subject: Pharmaceutical Sciences Degree

- Start date: 10, 1989
- End date: 01, 1995
- Qualification: Licenciatura in Pharmaceutical Sciences, PharmD
- Organisation: Faculty of Pharmacy of the University of Lisbon
- Country: Portugal
- Subjects/Skills: basic sciences (mathematics, physics, human biology), pharmaceutical technology, pharmacokinetics, pharmacology, several areas of applied analytical chemistry (food, water, phyto-chemistry, toxicology), practical work in inorganic and organic chemistry, biology (including, microbiology) laboratories and pilot scale pharmaceutical preparations.

## Training Courses

- Several QWP training courses on sterile manufacture, efficient and effective quality assessment, API starting materials, co-crystals, design space, description of the manufacturing process, NIRS, oral modified release products & dissolution of immediate release products, transdermal patches, real time release control strategy, ICH Q3D elemental impurities, quality assessment of drug substances, mathematical models, ICH Q3D, guideline on the selection of sterilisation processes for active substances, drug products and primary packaging, GMP related aspects, ICH M7, quality overview, drug-device combination products, dissolution specification for generics reflection paper, guideline on quality and bio-equivalence of topical products, guideline on maximum shelf-life for sterile products for human/veterinary use after first opening or following reconstitution – implementation issues, ICH Q12, nitrosamines, continuous manufacturing, synthetic peptides, transdermal patches, nanomedicines, GMP in quality assessment.
- Workshop CEP of the future, EDQM (2022).
- Quality trials regulation: quality assessment (IMPD), EU NTC / Czech Republic Competent Authority (2017).
- Clinical trial quality's assessor's meeting, Swedish Competent Authority (2008) and Czech Republic Competent Authority (2012).
- Quality risk management, mitigating risks to patients, delivering quality by design, 4Tune Engineering, Lda (2015).
- Joint regulators / Industry QbD workshop, EMA (2014).
- Quality by Design (QbD) & Process Analytical Technology (PAT) in the Pharmaceutical Industry, 4Tune Engineering, Lda (2012).
- Design of experiments general course, UMETRICS (2012).
- Multivariate data analysis general course, UMETRICS (2011).
- Integrated implementation workshops for ICH Q8, Q9 and Q10, Tallinn, Estonia (2010).
- Workshop on the Guideline on pharmaceutical development of medicines for paediatric use, EMA (2014).
- Workshop on paediatric formulations in national regulatory agencies, EMA (2010).
- 1<sup>st</sup> PDA Europe Meeting with sessions covering automation & robotics, testing of parenterals, blow-fill-seal, big data processing / Industry 4.0, continuous manufacturing & flexible facilities, lifecycle management and innovation, past & future of injectable dosage forms (2016).
- TOPRA training course at INFARMED (2016).
- DIA EuroMeetings (2005, 2006).
- Finish Presidency Conference on Nanotechnologies (2005).

## Additional information

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### Publications

### Projects

### Memberships

- Member of the Portuguese Medicines Evaluation Committee.
- Member of the Sub-Committee of Quality Experts of INFARMED.
- Member from Portugal of EMA's Quality Working Party (QWP).
- Member of the Portuguese Pharmaceutical Society.

## Other Relevant Information