



**Europass
Curriculum Vitae**

Personal information

First name(s) / Surname(s)

Annarita Meneguz

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Occupational field

Farmacotoxicological Research and Evaluation

Work experience

Dates

1998 -date

Occupation or position held

Head of the Unit of Biochemical Pharmacology and Technical Scientific Advice
Coordination Unit Department of Drug Research and Evaluation Istituto
Superiore di Sanità (*The Italian National Institute of Health/Governmental*)

Main activities and responsibilities	<p>As the head of one of the Drug research and Evaluation Department involved in centralised, decentralised and Mutual recognition procedure (dossier evaluation Module IV) and control (biological test : abnormal toxicity. Histamine release, Hypotension induction, according to EUP), the main responsibility is to assure that all these activities are performed according to the AQ unit procedure of the Department. Moreover as a member of the Scientific Secretary of the Italian Competent authority form Phase I Clinical Trial authorization I am in charge of Rapportership of anticancer and monoclonal antibody Investigational medicinal product dossier (IMPD).</p> <p>The main activities and responsibilities can be summarised as follows:</p> <ul style="list-style-type: none"> - Budget and human resources management; - Interaction with the Italian Agency for Medicines (AIFA) - Signature of all assessment of Module IV of the Department - Signature of the biological test results (certificate) - Responsibility of the transmission outside the Institute [mainly to the Osservatorio Nazionale sulla Sperimentazione Clinica con i Medicinali – OsSC -(National Monitoring Centre on Clinical Research with Medicines) at the AIFA. <p>Furthermore, the following activities and positions should be considered (in brackets date since when the position is held. All these positions are still hold.</p> <ul style="list-style-type: none"> - Italian Member of Safety Working Party of the Committee for Proprietary Medicinal Products (CHMP), European Medicines Agency (form 1998 see below). - Italian Member of OECD GL Working Group from 2010 - Italian expert for OECD for Human Health effect (form 1994) - Expert of the Italian Working Party on Radiopharmaceuticals (from 2008). - Junior GLP inspector (from 1992 to 1998) - Senior/Coordinator GLP Inspector (from 1999-2010) - Expert GMP Inspection only for radiopharmaceuticals (form 2005)
Name and address of employer	Istituto Superiore di Sanità - Viale R. Elena 299 - 00161 - Roma
Type of business or sector	Italian National Public Health Institute
Dates	1979-1998
Occupation or position held	Research Scientist in the Pharmacology Department Istituto Superiore di Sanità
Main activities and responsibilities	Research fields Neurotoxicity and Cyp 450 Metabolism
Name and address of employer	Istituto Superiore di Sanità - Viale R. Elena 299 - 00161 - Roma
Type of business or sector	Italian National Public Health Institute – Italian Official Medicines Control Laboratory
Dates	1998-date
Occupation or position held	Head of Unit of Preclinical Assessment and Phase I Clinical Trials Department of Drug Research and Evaluation of Istituto Superiore di Sanità GLP inspection activities within the Istituto Superiore di Sanità and Ministero della Salute (Ministry of Health)

Main activities and responsibilities	Italian Member of OECD GLP Working Group Handling of the GLP inspection requests by Ministry of Health Performing GLP inspections (reports) GLP Training of observers and junior inspectors Participation in the national and international (OECD) GLP activities Phase I IMPD dossier evaluation Radiopharmaceutical expert																																								
Name and address of employer	Drug Research and Evaluation Department , Istituto Superiore di Sanità, Viale Regina Elena 299, 00161 Roma, Italy																																								
Type of business or sector	Italian National Public Health Institute																																								
Education and training																																									
Dates	1974																																								
Title of qualification awarded	Degree in Biological Science																																								
Principal subjects/occupational skills covered	Thesis and research on biochemical of fat acids																																								
Name and type of organisation providing education and training	University "La Sapienza", Roma, Italy																																								
Personal skills and competences																																									
Mother tongue(s)	Italian																																								
Other language(s)	English																																								
Self-assessment <i>European level (*)</i>																																									
English	<table border="1"> <thead> <tr> <th colspan="4">Understanding</th> <th colspan="4">Speaking</th> <th colspan="2">Writing</th> </tr> <tr> <th colspan="2">Listening</th> <th colspan="2">Reading</th> <th colspan="2">Spoken interaction</th> <th colspan="2">Spoken production</th> <th colspan="2"></th> </tr> </thead> <tbody> <tr> <td>B 1</td> <td></td> <td>B 2</td> <td></td> <td>B 2</td> <td></td> <td>B 2</td> <td></td> <td>C 1</td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Understanding				Speaking				Writing		Listening		Reading		Spoken interaction		Spoken production				B 1		B 2		B 2		B 2		C 1											
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B 1		B 2		B 2		B 2		C 1																																	
	(*) Common European Framework of Reference for Languages																																								
Organisational skills and competences	Competences in the management of a Department Unit, Coordination of working groups.																																								
Technical skills and competences	Competent in biochemical and enzymatic techniques suitable for investigate neurotoxicity and drug metabolis.																																								
Computer skills and competences	good command of Microsoft Office™ tools (Word™, Excel™ and PowerPoint™) for Windows PC																																								
Other skills and competences	Reviewer for Italian Toxicological Society journal Participation to national and European project research projects																																								

Additional information**Research Interest**

Toxicity/Neurotoxicity

Metabolism

Main Scientific publications (2005-2010)

1. **Meneguz A.** Valutazione preclinica dei vaccini. In: Cantelli Forti G, Hrelia P, ed. *Le biotecnologie e la qualità della vita*. Bologna: Patron editore; 2005. p. 103-128.
2. Gribaldo L, Gennari A, Blackburn H, Clemenson C, Deguercy A, **Meneguz A**, Pfaller W, Ruhdel I. Acute toxicity. *Alternatives to laboratory animals: ATLA*. 2005;33(Suppl 1):27-34.
3. Prieto P, Clemenson C, **Meneguz A**, Pfaller W, Sauer UG, Westmoreland C. Subacute and subchronic toxicity. *Alternatives to laboratory animals: ATLA*. 2005;33(Suppl 1):109-116.
4. Coecke S, Blaauboer B, Elaut G, Freeman S, Freidig A, Gensmantel N, Hoet P, Kapoulas VM, Ladstetter B, Langley G, Leahy D, Mannens G, **Meneguz A**, Monshouwer M, Nemery B, Pelkonen O, Pfaller W, Prieto P, Proctor N, Rogiers V, Rostami-Hodjegan A, Sabbioni E, Steiling W, van de Sandt JJ. Toxicokinetics and metabolism. *Alternatives to laboratory animals: ATLA*. 2005;33(Suppl 1):147-175.
5. Cometa MF, Lorenzini P, Fortuna S, Volpe MT, **Meneguz A**, Palmery M. In vitro inhibitory effect of aflatoxin B1 on acetylcholinesterase activity in mouse brain. *Toxicology*. 2005;206(1):125-135.
6. Buratti FM, D'Aniello A, Volpe MT, **Meneguz A**, Testai E. Malathion bioactivation in the human liver: the contribution of different cytochrome P450 isoforms. *Drug metabolism and disposition*. 2005;33(3):295-302.
7. Di Consiglio E, **Meneguz A**, and Testai E. Organophosphorotation pesticides inhibit bioactivation of imipramine by human hepatic cytochrome P450s. *Toxicol. Appl. Pharmacol.* 2005; 15, 237-246.
8. Coecke S, Ahr H, Blaauboer B, Bremer S, Casati S, Castell J, Combes R, et al., **Meneguz A**, Testai E. Metabolism: a bottleneck in in vitro toxicological test development. The report and recommendations of ECVAM workshop 54. *Alternatives to laboratory animals: ATLA*. 2006; 34(1):49-84.
9. Cholinesterase inhibition and alterations of hepatic metabolism by oral acute and repeated chlorpyrifos administration to mice. Cometa MF, Buratti FM, Fortuna S, Lorenzini P, Volpe MT, Parisi L, Testai E, **Meneguz A** *Toxicology*. 2007 Feb 23.

Capitolo di Libri

1. Autorità regolatorie e processo registrativo di nuovi farmaci antineoplastici (Stefano Vella, **Annarita Meneguz**).in *Sviluppo dei farmaci oncologici con bersaglio molecolare: dalla tradizione all'innovazione* (a cura di Dino Amadori). Paletto editore. 2007
2. **A. Meneguz** Valutazione preclinica dei vaccini. *Biotecnologie e qualità della vita*. A cura di G. Cantelli forti e P. Hrelia . Patron editore 2005.
3. *Advanced Therapy: rules and experiences of the Phase I Italian Competent Authority*. **Annarita Meneguz**, Dipartimento del Farmaco ISS, Pharmaceuticals Policy and Law, 2014
4. **A. Meneguz**, MF Cometa Verso una revisione della Direttiva 2001/20 e una maggiore armonizzazione europea dei trial clinici precoci. In *Rapporti ISTISAN: 12/37Attività e impegno dell'Istituto Superiore di Sanità nella lotta contro il cancro*. 2014

Libri

Sperimentazione e registrazione dei radio farmaci Normative e procedure
Springer ED 2013, A cura di Lucignani, Nicotra e Meneguz

Evaluation Activity

- Number of Non Clinical Assessment Report for European procedures (Centralised, decentralised , Mutual Recognition): 250
- Number of IMPD Phase 1 assessment: 350
- Number of GLP inspection: > 70
- Radiopharmaceutical Assessment Report: 32 (CHMP Core Procedure), 10 new procedure

Rome, 03/03/2015

Signature
Dr. Annarita Meneguz