



**Europass  
Curriculum Vitae**

*Agenzia Italiana del Farmaco*

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**Personal information**

First name(s) / Surname(s)

Annarita Meneguz

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Nationality

Italian

Date of birth

October 29, 1952

Gender

Female

**Occupational field**

Farmacotoxicological Research and Evaluation

**Work experience**

Dates

1998 -date

Head of the Preclinical Assessment and Phase 1 Clinical trials Unit, Department of Drug research and Evaluation

## Main activities and responsibilities

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 for Phase I Clinical Trial authorization I am in charge of Rapportership of anticancer and monoclonal antibody Investigational medicinal product dossier (IMPD).

The main activities and responsibilities can be summarised as follows:

- 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.

Furthermore, the following activities and positions should be considered (in brackets date since when the position is held. All these positions are still hold.

- Italian Member of Safety Working Party of the Committee for Proprietary Medicinal Products (CHMP), European Medicines Agency (from 1998 up now).
- Italian Member of OECD GL Working Group from 2010 up now
- Italian expert for OECD for Human Health effect (from 1994)
- Expert of the Italian Working Party on Radiopharmaceuticals (from 2008).
- Junior GLP Inspector (from 1992 to 1998)
- Senior/Coordinator GLP Inspector (from 1999-up now)
- Expert GMP Inspection only for radiopharmaceuticals (from 2005)

Name and address of employer  
Type of business or sector

Istituto Superiore di Sanità - Viale R. Elena 299 - 00161 - Roma  
Italian National Public Health Institute

Dates

1979-1998

Occupation or position held

Dirigente Tecnologo dell'Istituto Superiore di Sanità  
Istituto Superiore di Sanità

## Main activities and responsibilities

Research fields Neurotoxicity and Cyp 450 Metabolism  
Institutional duties: Non clinical Assessor, GLP Senior Inspector, GMP Expert Inspector only for radiopharmaceuticals medicine I

Name and address of employer  
Type of business or sector

Istituto Superiore di Sanità - Viale R. Elena 299 - 00161 - Roma  
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  
Radiopharmaceutical expert  
Italian Member of CHMP/SWP/EMA  
Phase I IMPD dossier evaluation  
CTD dossier evaluation  
Nationale and EMA Non clinical Scientific advice assessment

**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** Public National 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**  
*European level (\*)*

**English**

Understanding				Speaking				Writing	
Listening		Reading		Spoken interaction		Spoken production			
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 (2005-2012)

1. Meneguz A. Valutazione preclinica del vaccini. In: Cantelli Forti G, Hrella 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, Degueray A, Meneguz A, Pfalter W, Ruhdel I. Acute toxicity. *Alternatives to laboratory animals: ATLA*. 2005;33(Suppl 1):27-34.
3. Priele P, Clemenson C, Meneguz A, Pfalter W, Sauer UG, Westmoreland C. Subacute and subchronic toxicity. *Alternatives to laboratory animals: ATLA*. 2005;33(Suppl 1):109-116.
4. Coecke S, Blaauw B, Elaut G, Freeman S, Freidig A, Gensmantel N, Hoel P, Kapoulas VM, Ladsleiter B, Langley G, Leahy D, Mannens G, Meneguz A, Monshouwer M, Nemery B, Petkonen O, Pfalter W, Priele P, Proctor N, Rogiers V, Roslami-Hodjegan A, Sabbioni E, Stelling 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. Organophosphorothionate pesticides inhibit bioactivation of Imipramine by human hepatic cytochrome P450s. *Tox. Appl. Pharmacol.* 2005; 15, 237-246.
8. Coecke S, Ahr H, Blaauw B, Bremer S, Casali S, Castelt 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 del farmaci oncologici con bersaglio molecolare: dalla tradizione all'innovazione (a cura di Dino Amadori). Paolillo editore. 2007.
2. A. Meneguz Valutazione preclinica del vaccini. Biotecnologie e qualità della vita. A cura di G. Cantelli Forti e P. Hrella. Patron editore 2005.
3. The EUROPEAN ADVANCED TRANSLATIONAL RESEARCH INFRASTRUCTURE IN MEDICINE EATRIS-WP8 First-In-Man (FIM) Regulatory Manual (FINAL VERSION). Giovanni Miglaccio, Annarita Meneguz, M.G. Galli; F. Belardelli, 2009
4. Advanced Therapy: rules and experiences of the Phase I Italian Competent Authority. Annarita Meneguz, Dipartimento del Farmaco, Istituto Superiore di Sanità ISS, Pharmaceuticals Policy and Law, 12: 29-33, 2010
5. Il Farmaco di origine chimica Annarita Meneguz "Alla ricerca del farmaco perduto, Autore C. Tomino, Medi Service ed 2011
6. Non clinical: need of studies on juvenile animals in order to evaluate the toxic potential before any administration to pediatric population, Annarita Meneguz, Dipartimento del Farmaco Istituto Superiore di Sanità, In Changes in Research and Development of Medicinal Products since the Paediatric Regulation [http://cdn.intechopen.com/pdfs/24649/InTech-Changes\\_in\\_research\\_and\\_development\\_of\\_medicinal\\_products\\_since\\_the\\_paediatric\\_regulation.pdf](http://cdn.intechopen.com/pdfs/24649/InTech-Changes_in_research_and_development_of_medicinal_products_since_the_paediatric_regulation.pdf)

## Evaluation Activity

- Number of Non Clinical Assessment Report for European procedures (National, Centralised, decentralised, Mutual Recognition): 250
- Number of IMPD Phase 1 assessment: 100
- Number of GLP inspection: 250
- Radiopharmaceutical Assessment Report: 32 (CHMP Core Procedure), 10 new procedure

Rome, 12 /07/2012

Signature

Dr. Annarita Meneguz

