



## Curriculum Vitae

### Personal information Panagiota Tsantili

#### Work experience

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1. Employer: National Organization for Medicines
  - Start date: 06-2009
  - End date:
  - Position: Deputy Head, Section of Biological Products, Evaluation Division (October 2023 - )
  - Activities: Quality, Non\_Clinical and Clinical assessment of biological products [Biologicals of recDNA origin, Neurotoxins, Blood products (Coagulation factors, Intravenous Immunoglobulins), Vaccines].
  - Scientific Board of approvals for Biological products (national applications): Scientific Secretary (October 2018-June 2023).
  - Biosimilar Medicinal Products Working Party (BMWP) Observer Appointment: October 2010 - May 2023.
  - Biologics Working Party (BWP) Alternate member: June 2014 - March 2023. Member: June 2023-present.
  - HMA, Biosimilar Working Group (BSWG) Member : Sept. 2021- present
  - Country: Greece
2. Employer: Ministry of Health and Social Solidarity
  - Start date: 10-2006
  - End date: 06-2009
  - Position: Division of Medicines and Pharmacies
  - Activities: Pharmacist, Section of Opioid Analgesics
  - Country: Greece
3. Employer: Technological Educational Institute of Athens (TEI), Dept. of Medical Laboratories.
  - Start date: 09-2003
  - End date: 06-2005
  - Position: Teaching position, (Associate Professor level)
  - Activities: Course in Biology
  - Country: Greece
4. Employer: Massachusetts General Hospital\_Harvard Medical School, Dept. of Surgery, Antibody Engineering Laboratory \_ Boston, MA
  - Start date: 02-2000
  - End date: 11-2001
  - Position: Post\_Doctoral Research Fellow.
  - Activities: Refinement of recombinant antibody structure for immunotherapy. Insertional mutagenesis in CDR loops to modify the specificity of antidigoxin Fab fragments. Identification of antigenic epitopes of Streptokinase (SK).
  - Country: United States
5. Employer: Boston University School of Medicine, Section of Molecular Genetics, Cardiovascular Institute, Boston, MA
  - Start date: 04-1998
  - End date: 01-2000
  - Position: Post\_Doctoral Research Fellow
  - Activities: Structure\_function analysis of the transcription activation domains of Hepatocyte Nuclear Factor 4
  - Country: United States

#### Education and training

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1. National & Kapodistrian University of Athens, Department of Biology
  - Start date: 08-1993
  - End date: 04-1998
  - Qualification: Ph.D. Degree
  - Ph.D. thesis title: "Recombinant Monoclonal Antibodies against the Acetylcholine Receptor" . Molecular mechanisms of autoimmunity, pathophysiology of Myasthenia Gravis, generation and biological characterization of recombinant mAb fragments, structural analysis of mAbs for receptor binding, AChR receptor\_mAb interactions
  - Country: Greece
2. Aristotle University of Thessaloniki, Department of Chemistry, Section of Biochemistry.
  - Start date: 07-1991
  - End date: 10-1992
  - Qualification: Research Assistant
  - Project title: "Establishment of Assay Conditions for Human Pancreatic Lipase". Lipase activity determination, enzyme purification techniques.
  - Country: Greece
3. Aristotle University of Thessaloniki, Department of Pharmacy.
  - Start date: 09-1987
  - End date: 07-1991
  - Qualification: Bachelor Degree in Pharmacy
  - Country: Greece

TRAINING

1. Subject: BMWP/BWP joint assessors training on assessment of similar biological medicinal products containing monoclonal antibodies
  - Start date: 10-2012
  - Qualification: Training
  - Organisation: EMA
  - Country: United Kingdom
2. Subject: Dendrimers as Composites of Advanced Drug Delivery nano Systems (aDDnSs): Biomedical Applications
  - Start date: 10-2011
  - Qualification: Training School and workshop
  - Organisation: National and Kapodistrian University of Athens, Dept. of Pharmacy, National Research Foundation, Athens
  - Country: Greece
3. Subject: Blood Products Assessors training (BPWP) Webinar
  - Start date: 09-2011
  - Qualification: Training
  - Organisation: EMA
  - Country: United Kingdom
4. Subject: Assessor's Training on Advance Therapy Medicinal Products
  - Start date: 04-2011
  - Qualification: Training
  - Organisation: EMA
  - Country: United Kingdom
5. Subject: Common Assessment Framework: Total Quality Management Tool
  - Start date: 03-2011
  - Qualification: Training
  - Organisation: National Centre for Public Administration & Local Government (E.K.D.D.A.), Athens
  - Country: Greece
6. Subject: FEBS "ADVANCED COURSE ON GENE THERAPY"
  - Start date: 10-1995
  - Qualification: Training
  - Organisation: FEBS course
  - Country: Varena, Italy
7. Subject: Advanced Study Course "MOLECULAR MECHANISMS OF TRANSCELLULAR SIGNALLING: From the Membrane to the Gene.
  - Start date: 08-1994
  - Qualification: Training
  - Organisation: "FEBS/NATO Summer School,
  - Country: Spetsai, Greece

## Additional information

### Publications

1. Kurki P, Barry S, Bourges I, Tsantili P, Wolff\_Holz E. Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective. *Drugs*. 2021 Oct 1. doi: 10.1007/s40265\_021\_01601\_2
2. Aggelidou E, Iordanidou P, Tsantili P, Papadopoulos G, Hadzopoulou\_Cladaras M. Critical role of residues defining the ligand binding pocket in hepatocyte nuclear factor\_4a (HNF\_4a). *J Biol Chem*. 2004 Jul 16; 279 (29): 30680\_8.
3. Parhami\_Seren B, Seavey M, Krudysz J, Tsantili P. Structural correlates of a functional streptokinase antigenic epitope: serine 138 is an essential residue for antibody binding. *J Immunol Methods*. 2003 Jan 15;272(1\_2):93\_105.
4. Krykbaev RA, Tsantili P, Jeffrey PD, Margolies MN. Modifying specificity of antidigoxin antibodies using insertional mutagenesis. *Protein Sci*. 2002 Dec;11 (12):2899\_908.
5. Hadzopoulou\_Cladaras M, Aggelidou E, Iordanidou P, Tsantili P. Mutations in the ligand binding domain (LBD) of hepatocyte nuclear factor 4 alpha (HNF\_4 alpha) affect transcriptional activation and coactivator interaction. *Circulation*, Nov. 5 2002;106 (19): 832 Supplement
6. Parhami\_Seren B, Krudysz J, Tsantili P. Affinity panning of peptide libraries using anti\_streptokinase monoclonal antibodies: selection of an inhibitor of plasmin(ogen) active site. *J Immunol Methods*. 2002 Sep 15;267(2):185.
7. Kardassis D, Falvey E, Tsantili P, Hadzopoulou\_Cladaras M, Zannis V. Direct physical interactions between SP1 and HNF\_4 mediate synergistic transactivation of the Apolipoprotein C III promoter. *Biochemistry*. 2002 Jan 29;41(4):1217\_28.
8. Kistanova E, Dell H, Tsantili P, Falvey E, Cladaras C, Hadzopoulou\_Cladaras M. The AF\_1 domain of HNF\_4 is an acidic activator that mediates interactions through bulky hydrophobic residues. *Biochem. J*, 2001;356:635\_42.
- 9\*. Poulas K, Tsibri E, Kokla A, Papanastasiou D, Tsouloufis T, Marinou M, Tsantili P, Papapetropoulos T, Tzartos SJ. Epidemiology of myasthenia gravis in Greece. *J of Neurol Neurosurg Psychiatry* 2001;71:352\_56.
10. Kardassis D, Falvey E, Tsantili P, Hadzopoulou\_Cladaras M, Zannis V. Direct physical interactions between SP1 and HNF\_4 mediate synergistic transactivation of the Apolipoprotein CIII promoter. *Circulation*, Oct 31 2000; 102 (18): 1440 Supplement
11. Kontou M, Leonidas DD, Vatzaki EH, Tsantili P, Mamalaki A, Oikonomakos NG, Acharya KR, Tzartos SJ. The crystal structure of the Fab fragment of a rat monoclonal antibody against the main immunogenic region of the human muscle acetylcholine receptor. *Eur J Biochem*. 2000;267(8):2389\_97.
12. Poulas K, Tsibri E, Papanastasiou D, Tsouloufis T, Marinou M, Tsantili P, Papapetropoulos T, Tzartos SJ. Equal male and female incidence of myasthenia gravis. *Neurology*. 2000;54(5):1202\_3.
13. Tsantili P, Tzartos SJ, Mamalaki A. High affinity antibody fragments protecting the human nicotinic acetylcholine receptor. *J. Neuroimmunol* 1999;94:15\_28.
14. Tzartos SJ, Barkas T, Cung MT, Mamalaki A, Marraud M, Orlewski P, Papanastasiou D, Sakarellos C, Sakarellos\_Daitsiotis M, Tsantili P, Tsikaris V. Anatomy of the antigenic structure of a large membrane autoantigen, the muscle\_type nicotinic acetylcholine receptor. *Immunol Rev*. 1998 Jun;163:89\_120
15. Tzartos SJ, Tsantili P, Papanastasiou D, Mamalaki A. Construction of single\_chain Fv fragments of anti\_MIR monoclonal antibodies. *Ann N Y Acad Sci*. 1998;841:475\_7.
16. Tsantili P., Mamalaki A. and Tzartos S Construction of a single chain Fv antibody (scFv195) fragment against the human Acetylcholine receptor. Contribution of light chain amino acid residues in receptor recognition". *Immunology Letters* 1997 May; 56 (Part 2).
17. Tzartos SJ, Cung MT, Mamalaki A, Marraud M, Papanastasiou D, Sakarellos C, Sakarellos\_Daitsiotis M, Tsantili P.

Antigenic structure of the muscle nicotinic acetylcholine receptor. Ann Med Interne. 1996, 147(6):442\_6

18. Arzoglou P, Goudoula C, Tsantili P, Lessinger JM, Ferard G, Mignot V, Samyn N, Demeester J, Lauwers A, Brettschneider H, et al. Transferability of lipase titrimetric assays: deductions from an interlaboratory study. Eur J Clin Chem Clin Biochem 1994;32(10):773\_7

\* Authors of the manuscript are recipients of Honorary Award from National and Kapodistrian University of Athens.

#### Projects

#### Memberships

#### Other Relevant Information

LANGUAGES: GREEK (native speaker) OTHER LANGUAGES: ENGLISH Excellent (reading, writing and verbal skills)