

PERSONAL INFORMATION

Klaus Cichutek

WORK EXPERIENCE

December 2009–Present

President

Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines (Germany)

Legal responsibility for the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany, its regulatory and research activities, with about 800 staff members including medical doctors and scientists, under the auspices of the German Federal Ministry of Health

March 1998–Present

Adjunct Professor of Biochemistry (apl. Prof.)

Johann Wolfgang von Goethe - Universität (Germany)

Experimental research and teaching activities (lab courses, university lectures in virology and medical biotechnology) for students of biochemistry and medicine

October 2001–November 2009

Vice-President

Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines (Germany)

Deputy directorship of the Paul-Ehrlich-Institut, research and regulatory responsibilities in advanced therapy medicinal products, management of internal institute affairs

November 1994–September 2011

Head of Medical Biotechnology Division

Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines (Germany)

Regulation of advanced therapy medicinal products, policy advice, research in gene therapy and virology

March 1992–November 1994

Head of Section

Paul-Ehrlich-Institut (Germany)

Regulation of gene therapy medicinal products and xenotransplantation, policy advice, research in gene therapy and virology

October 1988–March 1992

Head Research Group

Paul-Ehrlich-Institut (Germany)

Experimental research on oncogenic retroviruses and on human and simian immunodeficiency viruses

January 1985–September 1988

Postdoctoral fellow

University of California, Berkeley, Department of Molecular Biology and Virus Laboratory, on a fellowship of the (United States)

Experimental research on cancer and oncogenic retroviruses, funded by an educational grant by the German Science Foundation, later by a grant from the University of California, in the "Molecular Biology and Virus Laboratory" of the University of California, Berkeley

EDUCATION AND TRAINING

1992–Present

Privatdozent and habilitation (University Lecturer)

Faculty of Biochemistry, Pharmacy and Food Chemistry, Johann Wolfgang von Goethe - Universität (Germany)

Official title in Germany provided by universities, equivalent to assistant professorship qualification, requiring continuous successful experimental research activities (proven by a defined level of

research publications in international peer reviewed scientific journals) base on successfully acquired research grants (from public research foundations, Ministeries and European Commission)

1976–1984 **Diploma and Doctor of Life Sciences (Dr. rer. nat.) in Biochemistry, secondary subjects Pharmacology and Chemistry**

Universität Münster (Germany)

Study of chemistry and biochemistry finalized by a diploma in biochemistry ("sehr gut" (highest grade level) and a PhD (Dr. rer. nat.) in biochemistry ("summa cum laude" (highest grade level)

ADDITIONAL INFORMATION

Expertise

Regulatory expertise for biological medicinal products including vet and human vaccines and allergens, human sera and monoclonal antibodies, blood and tissue products, plasma-derived products, advanced therapy products.

Research expertise in virology, gene and cell therapy.

Publications

- Author of more than 100 publications in peer-reviewed scientific journals listed in pubmed.

- Examples for peer-reviewed publications listed in pubmed from the last 4 years:

A single amino acid substitution in the measles virus F₂ protein reciprocally modulates membrane fusion activity in pathogenic and oncolytic strains.

Heidmeier S, Hanauer JR, Friedrich K, Prüfer S, Schneider IC, Buchholz CJ, Cichutek K, Mühlebach MD.

Virus Res. 2014 Feb 13;180:43-8. Epub 2013 Dec 22.

A novel small animal model to study the replication of simian foamy virus in vivo.

Blochmann R, Curths C, Coulibaly C, Cichutek K, Kurth R, Norley S, Bannert N, Fiebig U.

Virology. 2014 Jan 5;448:65-73. Epub 2013 Oct 18.

Special considerations for the regulation of biological medicinal products in individualised medicine : More than stratified medicine.

Müller-Berghaus J, Volkens P, Scherer J, Cichutek K.

Bundesgesundheitsblatt Gesundheitsforschung. 2013 Nov;56(11):1538-44.

Prototype foamy virus Bet impairs the dimerization and cytosolic solubility of human APOBEC3G.

Jaguva Vasudevan AA, Perkovic M, Bulliard Y, Cichutek K, Trono D, Häussinger D, Münk C.

J Virol. 2013 Aug;87(16):9030-40. doi: 10.1128/JVI.03385-12. Epub 2013 Jun 12.

A global regulatory science agenda for vaccines.

Elmgren L, Li X, Wilson C, Ball R, Wang J, Cichutek K, Pfeleiderer M, Kato A, Cavaleri M, Southern J, Jivapaisampong T, Minor P, Griffiths E, Sohn Y, Wood D.

Vaccine. 2013 Apr 18;31 Suppl 2:B163-75.

DARPin-targeting of measles virus: unique bispecificity, effective oncolysis, and enhanced safety.

Friedrich K, Hanauer JR, Prüfer S, Münch RC, Völker I, Filippis C, Jost C, Hanschmann KM, Cattaneo R, Peng KW, Plückthun A, Buchholz CJ, Cichutek K, Mühlebach MD.

Mol Ther. 2013 Apr;21(4):849-59. Epub 2013 Feb 5.

Safety assessment of biolistic DNA vaccination.

Langer B, Renner M, Scherer J, Schüle S, Cichutek K.

Methods Mol Biol. 2013;940:371-88. Review.

Interaction of human immunodeficiency virus type 1 Vif with APOBEC3G is not dependent on serine/threonine phosphorylation status.

Kopietz F, Jaguva Vasudevan AA, Krämer M, Muckenfuss H, Sanzenbacher R, Cichutek K, Flory E, Münk C.

J Gen Virol. 2012 Nov;93(Pt 11):2425-30. Epub 2012 Aug 15.

Adherens junction protein nectin-4 is the epithelial receptor for measles virus.

Mühlebach MD, Mateo M, Sinn PL, Prüfer S, Uhlig KM, Leonard VH, Navaratnarajah CK, Frenzke M, Wong XX, Sawatsky B, Ramachandran S, McCray PB Jr, Cichutek K, von Messling V, Lopez M, Cattaneo R.

Nature. 2011 Nov 2;480(7378):530-3. doi: 10.1038/nature10639.

Clinical application of gene therapy. Previous experience and the future.

Langer B, Cichutek K.

Pharm Unserer Zeit. 2011 May;40(3):254-62. doi: 10.1002/pauz.201100421. Review. German.

Mutation of a diacidic motif in SIV-PBj Nef impairs T-cell activation and enteropathic disease.

Tschulena U, Sanzenbacher R, Mühlebach MD, Berger A, Münch J, Schindler M, Kirchoff F, Plesker R, Coulibaly C, Panitz S, Prüfer S, Muckenfuss H, Hamdorf M, Schweizer M, Cichutek K, Flory E.

Retrovirology. 2011 Mar 2;8:14. doi: 10.1186/1742-4690-8-14.

Restriction of porcine endogenous retrovirus by porcine APOBEC3 cytidine deaminases.

Dörrschuck E, Fischer N, Bravo IG, Hanschmann KM, Kuiper H, Spötter A, Möller R, Cichutek K, Münk C, Tönjes RR.

J Virol. 2011 Apr;85(8):3842-57. doi: 10.1128/JVI.01880-10. Epub 2011 Feb 9.

Projects

Memberships

▪ Previous memberships/chairmanships:

- chairman of the Commission of the Somatic Gene Therapy at the German Medical Association,
- chairman of the CHMP Gene Therapy Working Party (GTWP) of the European Medicines Agency (EMA),

- co-chairman of the ICH Gene Therapy Discussion Group,

▪ - co-chair of the BEMA Steering Group of the Heads of Medicines Agencies,

- member of the board of European Society of Gene and Cell Therapy (ESGCT) and several international research consortia.

Current memberships/chairmanships:

- founding member and coordinator of the German Centre for Infection Research, a German Health Research Center, since 2010,

- member of committees of the German Society of Virology,

- member of several editorial boards of scientific journals,

- board member of the German Consortium of Research Institutes of German Federal Ministries

- member of the Expert Committee for Biological Standardization (ECBS) of the WHO since 2012;

- member of the Product Development of Vaccines Committee of the WHO since 2014,

- chairman of the Management Group of the European Heads of Medicines Agencies (HMA) since 2014,

- in 2011-2014 alternate member, since 2015 member of the EMA Management Board..

Other Relevant Information

Prof. Dr. Klaus CICHUTEK is President of the Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, in Germany and apl. Professor of Biochemistry at the Goethe University in Frankfurt/Main. He received his Diploma and PhD in biochemistry from the Wilhelms-University in Muenster, Germany, in 1984. He then moved to the Molecular Biology and Virus Lab at the University of California in Berkeley, USA, supported by a postdoctoral fellowship from 1985 – 1988 awarded by the German Research Council (DFG). From 1988 to 2009, Professor Cichutek was first head of the research group "Molecular Biology" at the Paul-Ehrlich-Institut in Langen, Germany, then head of the "Medical Biotechnology" division and finally Vice President. Since December 2009, he has been President of the Paul-Ehrlich-Institut. From 2000 to 2009, Professor Cichutek was Chairman of the Commission of the Somatic Gene Therapy at the German Medical Association, Chairman of the CHMP Gene Therapy Working Party (GTWP) of the European Medicines Agency (EMA), and Co-chairman of the ICH Gene Therapy Discussion Group. He was member of the board of European Society of Gene and Cell Therapy (ESGCT) and several international research consortia. He currently is member of committees of the German Society of Virology, member of several editorial boards of scientific journals, he was co-chair of the BEMA Steering Group of the Heads of Medicines Agencies,

board member of the German Consortium of Research Institutes of German Federal Ministries and he has been summoned as member of the Expert Committee for Biological Standardization (ECBS) of the WHO in 2012 and 2013 and he has been selected as member of the Product Committee of Vaccine of the WHO since 2014. Since 2014 he is Chair of the Management Group of the European Heads of Medicines Agency. Having been alternate member, he is now German member of the EMA Management Board. His research activities focus on virology and biomedicines including vaccines, monoclonal antibodies, allergens, blood and tissue products, gene, cell therapy and tissue engineered products. Professor Cichutek is the author of more than 100 publications in peer-reviewed scientific journals as listed in pubmed.