Bundesinstitut für Impfstoffe
und biomedizinische Arzneimittel

Paul-Ehrlich-Institut

IPFA/PEI 25th International Workshop

"Surveillance and Screening of Blood-borne Pathogens"

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Klaus Cichutek
Micha Nuebling
Sally Baylis

Paul-Ehrlich-Institut
Langen, Germany

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Das Paul-Ehrlich-Institut ist ein Bundesinstitut im Geschäftsbereich des Bundesministeriums für Gesundheit.

The Paul-Ehrlich-Institut is an Agency of the German Federal Ministry of Health.

Paul Ehrlich

- 1891
  Appointed by Robert Koch to Director of the newly established Institute of Infectious Diseases in Berlin (today: Robert Koch Institut). Worked on the standardization of diphtheria serum

- 1897
  Publication of the side-chain theory:
  “The validation of the diphtheria therapy serum and its theroretical basis“.

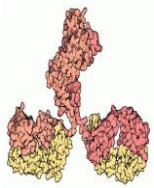
- 1908
  Nobel Prize awarded to
  Paul Ehrlich and Élie Metchnikoff
  “in recognition of their work on immunity”

Recent history of the Paul-Ehrlich-Institut

- 1972 Federal Agency for Sera and Vaccines
- 1994 Responsibility for blood and blood products
- 2000 IVD test laboratory
- 2003 IVD Directive
- 2004 GCP Guideline
- 2005 WHO Collaborating Centre for Quality Assurance of Blood Products and *In Vitro* Diagnostics
- 2007 Tissues Act
- 2013 WHO Collaborating Centre for Vaccines

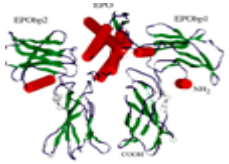
Biomedicines

Monoclonal antibodies
Immune Sera



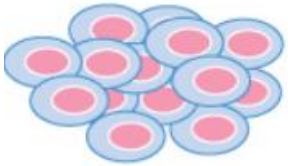
Vaccines

Plasma-derived clotting factors
Recombinant clotting factors

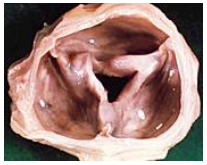


Gene therapy
medicinal products

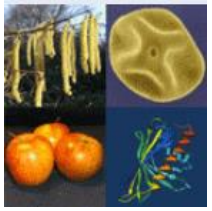
Blood products
for transfusion
medicine



Somatic cell therapy
products



Tissue-engineered products,
Tissue preparations



Allergens

Regulation of Biomedicines

- Quality and efficacy based on
  - selection of donors
  - testing of source materials
  - testing of final products

- Regulations assure „state of the art“ quality of biomedicines

  <u>precondition</u>
  suitable in vitro diagnostics (IVDs) and/or (bio)assays

  - Assessment of IVDs
    - IVD test laboratory at PEI (PEI IVD)
  - Validation of assays

Regulatory Measures for Viral Safety of Blood

1971	HBsAg
1985/6	anti-HIV 1/2
1991	anti-HCV
1999	HCV RNA minimal sensitivity: 5,000 IU/ml
2004	HIV-1 RNA minimal sensitivity: 10,000 IU/ml
2006	antiHBc
2014	West Nile Virus deferral of donors with travel history
2015	HIV-1 RNA two target regions
????	HEV RNA (?)

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Transfusion-transmitted Viral Infections 1997 – 2015

	97-98	99	00	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15	97 – 14
	HCV transmission																		
RBC	7	0*	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	**8**
PC	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**3**
FFP	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**9**
Total	**19**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**20**
	HIV transmission																		
RBC	1	0	3	0	0	0	0#	0	0	1	0	0	1	0	0	0	0	0	**6**
PC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
FFP	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	**0**
Total	**1**	**0**	**3**	**0**	**0**	**0**	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**0**	**0**	**0**	**0**	**6**
	HBV transmission																		
RBC	2	2	1	0	1	1	2	2	3+	1	1	0	0	0	0	0	0	1	**17**
PC	1	0	0	0	0	2	0	0	0	0	0	1	0	0	1	0	0	0	**5**
FFP	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	0	0	0	**3**
Total	**3**	**2**	**1**	**2**	**1**	**3**	**3**	**2**	**3**	**1**	**1**	**1**	**0**	**0**	**1**	**0**	**0**	**1**	**25**

* Implementation of HCV-NAT, # of HIV-NAT donor pool screening, + of anti-HBc donor screening

Regulatory Measures for Virus Safety

Confirmed virus transmissions before / after implementation

Target	Measure	Year of implementation	Transmission cases per million blood units	
			before	after
HCV	HCV NAT	1999	1.67	0.01
HIV	HIV-1 NAT	2004	0.1	0.04
HBV	antiHBc	2006	0.35	0.09

“Surveillance and Screening of Blood-borne Pathogens”

- The series of IPFA / PEI workshops (formerly “EPFA / NIBSC”) has been instrumental for worldwide progress in the field of blood and plasma safety
- Workshop discussions on
  - pathogens (old, new, emerging)
  - impact on blood and plasma safety
  - surveillance and potential for emergence
  - Countermeasures
    - testing technologies
    - donor deferral
    - removal / inactivation
  - risk analysis
  - decision making
- Representation of all stakeholders involved in blood safety
- Theo Evers, initiator of this unique global forum
  Rob van Tuyle, IPFA president, and Paul Strengers, Executive Director
  Micha Nuebling and Michael Chudy, PEI
- Helenic National Blood Transfusion Center (E.KE.A.)
- All sponsors

Imput from all stakeholders needed

- „State of the art“ regulation needs input from all stakeholders
  - Manufacturers, e.g.
    - blood establishments
    - plasma manufacturers
    - IVD manufacturers
  - Users
  - Patients
  - Scientists
  - Regulators
- PEI committed to future contribution to IPFA / PEI Workshops as an international forum for scientific exchange in the field of blood and blood products

Our Focus is on Health