

Jay M. Ehrlich MD

ABIM Board Certified 8/96, Re-Certified 08/06, 12/15



WORK EXPERIENCE

Baxter Healthcare 10/2005-Present

Vice President, Global Patient Safety 09/2013-Present

- Responsible for driving strategy and execution of:
 - a 140+ member global patient safety team handling clinical and post-market safety for all Baxter drugs and medical devices and its associated multimillion dollar budget
 - global approach to PV inspection and audit readiness
 - functional separation of Baxter/Baxalta (Bioscience division spinoff), including staff, processes and technology (2014-2015)
 - zero-based budgeting and zero-based organization activities, resulting in 2M+ annualized savings in Global Patient Safety function (2016)
 - shifted transactional work from high-cost to low-cost offshore center
 - technology platform shift (global safety database) to the cloud, resulting in 8M annualized savings in Global Patient Safety function (2017)
- R&D Representative to Corporate Responsibility Council with responsibility and accountability for R&D goals, including reduction of chemicals of concern and material waste reduction in Baxter drug and device products
- R&D Sponsor of Baxter Young Investigator Awards
- Early Career Professional Business Resource Group Steering Committee
- Cybersecurity Steering Committee

Vice President, Global Pharmacovigilance 09/2009-09/2013

- Responsible for driving strategy and execution of a 225+ member global patient safety team handling clinical and post-market safety for all Baxter drug, biologic and vaccine products and its associated multimillion dollar budget
- Responsible for leading multiple pharmacovigilance inspections with global regulators, including FDA, EMA, MHRA (UK), MPA (Sweden), BfArM (Germany)
- Responsible for strategic response formulation to global patient safety-related inquiries related to ex-US manufacturing plant contamination issue
- Company representative and expert witness, including 30+ days in federal and county courtrooms, in multiple heparin-related lawsuits

Senior Director, Global Pharmacovigilance 01/2007-09/2009

- Responsible for adverse event investigation, including hospital site visits, related to heparin oversulfated chondroitin sulfate (OSCS) active pharmaceutical ingredient adulteration. Included:

- Regular updates directly with FDA
- Onsite and telephone discussions with Centers for Disease Control (CDC)
- Fly-in to Washington, DC, to directly discuss heparin-related public health crisis with various members of Congress
- Interaction with internal and external preclinical and hematology experts
- Regular updates with internal and external legal council

Director, Safety Operations – Global Medical Vigilance 10/2005-12/2006

- Responsible for strategy and execution to remediate 50+ observation EMEA inspection and 5+ observation FDA inspection
- Responsible for US and EU safety operations staff, processes, and technology

Abbott Laboratories 04/2002-10/2005

Team Leader 05/2004-10/2005

- Responsible for managing team of 4 Clinical Safety physicians, in addition to retaining all adalimumab (Humira) clinical safety responsibilities

Associate Medical Director, Clinical Safety Evaluations 04/2002-10/2005

- Primary clinical safety physician for adalimumab (Humira) clinical safety across multiple clinical trials in multiple indications being sought
- Responsible for education and transition of post-market safety physician(s) on adalimumab (Humira) as it launched in US and EU

Suburban Medical Associates 01/1999-04/2002

Condell Medical Center – Physician Education Committee 2002
Urgent Care Committee 2001

Deerpath Medical Associates 1996-1999
Chairman, Executive Committee 1998-1999
Physician Order Entry Management Software Design Team 1997-1999
Physician Recruitment 1996-1998

Lake Forest Hospital – ER On-Call Task Force 1998-1999
Occupational Medicine 1996-1999

RESIDENCY TRAINING

Rush-Presbyterian-St. Lukes Medical Center 1993-1996
Internal Medicine Residency Program, Chicago, Illinois

EDUCATION

University of Chicago Pritzker School of Medicine
Chicago, Illinois

M.D., 1989-1993

University of Illinois
Champaign, Illinois

B.A., 1985-1989

S P E A K I N G

Parenteral Drug Association Keynote Speaker: What is Pharmacovigilance? Technovigilance? Why You Should Care...	Aug 09, 2018
Midwest Pharmacovigilance Network Keynote Speaker: Market Research Programs and Patient Support Programs – Challenges in the PV Setting	Dec 05, 2013
15 th Annual Registries and Post-Approval Studies Congress Speaker: Impact of the EU Pharmacovigilance Draft Guidance	Sep 21, 2012
DIA 2011, 47 th Annual Meeting Discussion Panelist/Speaker: Pharmacovigilance: How to do More with Less	Jun 22, 2011

C L I N I C A L R E A S E A R C H E X P E R I E N C E

TREAT Antibiotic Study, Principal Investigator	2001-2002
TARGET Cholesterol Study, Principal Investigator	1997-1998
L-TAP Cholesterol Study, Principal Investigator	1996-1997

N O N - C L I N I C A L R E S E A R C H E X P E R I E N C E

University of Chicago Pritzker School of Medicine Department of Gastroenterology; Dr. Steven Hanauer	1989-1993
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Identifying patients at risk of developing acute pancreatitis receiving 6-mercaptopurine therapy for Crohn's disease and ulcerative colitis.

S E L E C T T R A I N I N G S

Company Core Data Sheets and Core Safety Information Workshop - Pharmaceutics LLC	July 2007
The FDA Regulatory and Compliance Symposium: Managing Risks – From Pipeline to Patient - FDA News	Aug 2005
Draft Safety Surveillance and Epidemiology Training Source – DIA	Oct 2003

EXTRACURRICULAR ACTIVITIES

Lake County Board of Health, Vice President	2021-
Lake County Board of Health, Board Member	2015-2020
Medical Student Applicant Interviewer, Rush Medical College	1993-1995
Medical Student Applicant Interviewer, Pritzker School of Medicine	1991-1993
Pre-Orientation Committee, Pritzker School of Medicine	1990-1991
Teaching Assistant, Human Anatomy	1990-1991
Class Representative, Dean's Council	1989-1990
Early Start Date Committee, Pritzker School of Medicine	1989-1990
President, Alpha Epsilon Pi Fraternity	1987-1988

HONORS AND AWARDS

GRAPV Rewards and Recognition Program – Partnering Award	2008
Baxter Technical Award – Heparin Investigation	2007
GRAPV Rewards and Recognition Program – Partnering Award	2007
Jewish Vocational Service Scholarship	1991-1993
SPIRIT Award winner, Lutheran General Hospital	1991-1992
Phi Beta Kappa Society	1988-1989
Golden Key Honor Society	1988-1989

INTERESTS

Computer programming and system optimization, home electronics, multi-instrumental musician, in-line skating, pinball machine/video game repair, home improvement and repair.

PUBLICATIONS

Jacob, D., Marron, B., Ehrlich, J., & Rutherford, P. (2013). Pharmacovigilance as a tool for safety and monitoring: a review of general issues and the specific challenges with end-stage renal failure patients. *Drug, Healthcare and Patient Safety*, 5, 105-112.
doi:10.2147.DHPS.S43104