



Rob Kowalski **Executive Vice President, Head,** **Regulatory Affairs, Novartis, and US** **Head of Global Drug Development**

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Rob Kowalski is Executive Vice President and Head of Regulatory Affairs for Novartis and US Head of Global Drug Development. He serves on the US Country leadership team. Rob and his teams have successfully developed and registered over 100 new chemical entities, new indications, and devices across a wide array of therapeutic areas in the small molecule, biologics, biosimilar, and cell and gene therapy spaces.

Rob previously served as the Global Head of Development Medical Affairs for Novartis. Prior to that, he held regulatory leadership roles at Pharmacia (now Pfizer) and Schering-Plough (now Merck).

Rob is past Chair of PhRMA's Regulatory Affairs Committee and Vice Chairman of the Board of Directors for the R&D Council of New Jersey. He was a member of the U.S. Food and Drug Administration (FDA) Rare Disease Advisory Panel and an industry representative for both PDUFA V and VI FDA reauthorization negotiations. He is also a member of the Industry Pharmacists Organization Advisory Board and a past member of The Organization for Professionals in Regulatory Affairs Advisory Council.

Rob received a B.S. in Pharmaceutical Sciences and a Ph.D. in Pharmacy, both from the University of Wisconsin, Madison. He completed post-doctoral training at Rutgers University/Sandoz Pharmaceuticals and has trained at the Executive Forum of the Harvard Business School.