- **Name:** **Hue Kwon**
- **Current Position & Affiliation:** **VP, Quality Team, Samsung Bioepis**
- **Country:** **Republic of Korea**

• Educational Background:

1998 – 2002 Ph.D. in Biopharmaceutics & Minor in Statistics
College of Pharmacy, Oregon State University, Oregon, USA
1993 – 1998 B.S.E. in Biological Engineering
School of Engineering, In-ha University, South Korea

• Professional Experience:

April 2020 – Present **Samsung Bieopis, Incheon, South Korea**: Vice President, Quality Team

- Lead the quality team responsible for capability building and quality process improvement to strengthen health quality standards and procedures to meet US/EMA regulatory standards
- Be a member of executive leadership to advise senior leaders and CEO on strategic roadmap for build and sustain high quality system supporting the drug development lifecycle

May 2019 – Mar 2020 **NNIT AG, Zurich, Switzerland:** Managing consultant

- Manage global projects supporting life science digital transformation

Dec 2014 – Apr 2019 **F. Hoffmann-La Roche Ltd., Switzerland**
Oct 2017 – Apr 2019 Head Business Management

- A member of executive leadership team to develop global strategy to lead Roche core regulatory position on international personalized medicine policy
- Led 'Affiliate Operating Model' project to build the regulatory capabilities in the foreign governments in emerging countries to support market access of new drug

Oct 2014 – Sept 2017 Global Head Quality and Regulatory Compliance

- A member of executive leadership team providing governance and leadership of cross-functional quality and operational excellence

- Managed global team located in US, China and Switzerland to support outsourcing and interactions with international health authorities to position Roche drug development strategies to achieve approval and access in international market

Aug 2013 – Nov 2014 **Novartis AG, Switzerland**: Senior Compliance Professional

- A member of subject matter experts (SMEs) to identify regulatory barrier for achieving US drug product production and approval worldwide
- Led a team of regulatory data integrity, GMP and Product Quality and Computer System Validation (CSV) / IT SMEs to ensure drug development is met the relevant local standards and regulatory compliance to enable market access and supply chain.

Jan 2011 – Jul 2013 **HK Consulting, USA**: Senior Advisor Consultant

- Scientific advisor on regulatory, specifically clinical pharmacology and clinical endpoint studies and data integrity SME in due diligence projects and drug development activities monitoring and audit, develop and lead vendor oversight and QMS operational strategy

2002-2010 **US Food and Drug Administration (FDA), USA**: Clinical Pharmacologist

- Led the evaluation of the regulatory submission and inspections
- FDA representative in WHO workshop and guidance development working group
- Member of Office Director's scientific expert team
- Led science-based regulatory responses to citizen petition / US congress inquiry and assessment of regulatory submissions
- Worked on establishment or update of regulatory guidance and being the Biopharmceutical Classification System (BCS) committee member of CDER, leading biowaiver decisions

• Professional Organizations:

2014-2017	IQ Consortium
2014-2017	EFPIA EU 'Innovative Medicine Initiative' working group
2022-Present	Biophorum

• Main Scientific Publications:

Biopharmaceutics Applications in Drug Development (pp.262-289): S. Haidar, **H. Kwon**, R. Lionberger, L. Yu

Validation and application of a stability-indicating HPLC method for the in vitro determination of gastric and intestinal stability of venlafaxine, May 2007 J. of Pharmaceutical and Biomedical Analysis 43(5):1854-9: E. Asafu-Adjaye, P. Faustino, M. Tawakkul, L. Anderson, L. Yu, **H. Kwon**, D. Volpe

Impact of P-Glycoprotein-Mediated Intestinal Efflux Kinetics on Oral Bioavailability of P-Glycoprotein Substrates, November 2004Molecular Pharmaceutics 1(6):455-65: **H. Kwon**, R. Lionberger, L. Yu