

Adam Z. DAVID Ph.D., MBA

Head of Pharmaceutical Expert and Coordination Department

SUMMARY

With more than two decades of experience in pharmaceutical development, Adam has gathered outstanding overview and knowledge regarding the development of pharmaceutical drug products, and the quality requirements fulfilling different regulatory regions. During his work as a scientific expert, collected an ever-increasing applicable knowledge in the regulatory landscape mainly in the European, the American and the newly formed Eurasian pharmaceutical development arena, and collected knowledge regarding the Brazilian and Chinese requirements. He had participated as an advisor in the development of medical devices as well. He also had conducted due diligence processes of many different dosage forms and medical devices. He was tasked with leading different development teams, guiding, and aiding the scientists to achieve their goals in the best possible way. Today he is the head of a department, leading highly skilled scientists in aiding and coordinating development activities, CMC writing. Adam is quick, ingenious, stimulating, alert and outspoken. He is resourceful in solving new and challenging problems. He is adept at generating conceptual possibilities and then analysing them strategically. He is however bored by routine, and if possible, will seldom do the same thing the same way. Further, he constantly seeks the opportunity to deepen and perfect his knowledge collected and has the drive to share said knowledge with colleagues and/or customers.

CONTACT



H-1015 Budapest, Batthyany street 12., Hungary



+36 20 342 3070



dadam75@gmail.com



linkedin.com/in/adam-david-ph-d-mba-75491611/

Thesis: "Application possibilities of light reflecting experiments in pharmaceutical technology" (in Hung.)

AREAS OF EXPERTISE

- Drug product development
- Design of Experiments
- GMP, MDR, ISO
- Agile methodology (SCRUM)
- Problem focused thinking
- Quality by Design (QbD)
- CMC writing and evaluation
- Documenting work
- Training others
- People's management

COMPETENCIES

- Planning and executing experimental work, collecting and analysing results, drawing conclusions
- Providing scientific support to development teams. I have introduced risk base approach to development (based on QbD) and was able to reduce the number of necessary experiments, thus saving money while keeping high quality development.
- I have initiated and carried out technology training of QA personnel to help communication between the two fields.
- I am often asked for advice in quality related issues base on technology problems of licence in products during dossier renewal, or in case of OOX failures.
- I pioneered in developing an orodispersible tablet, the first ever prepared in Egis.
- I have led people transferred under my command as a scientific expert. I have trained new recruits, organized, and controlled their work.

EDUCATION

- Master of Business Administration (MBA) 2013-2015.
Budapest Technical University
Thesis: "GMP and ISO. Is the voluntary quality assurance system necessary in addition to the mandatory one?" (in Hung.)
- Ph.D. degree in pharmaceutical sciences 2000-2006.
Semmelweis University, Budapest
Thesis: Application of microwave and near infrared electromagnetic radiation in recent pharmaceutical technological procedures and investigations" (in Hung.)
- M.Sc. in pharmaceutical sciences 1995-2000.
Semmelweis University, Budapest

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WORK EXPERIENCE

- Head of Pharmaceutical Expert and Coordination Department
Egis Pharmaceuticals PLC 2023-Present
Responsibilities: providing scientific support as previously, plus the management of the newly formed department, including, but not limiting to people's management, -development, -evaluation, etc.
- Scientific expert of pharmaceutical development
Egis Pharmaceuticals PLC 2016-2023.
Responsibilities: scientific support, evaluation of product and process development ideas, building the theoretical bases for product development of new product candidates. Constructing and evaluating experimental design plans, performing scientific based risk assessments, and risk re-evaluations. CMC writing, IND document preparation. Due-diligence, evaluating licence-in documentations for drugs and medical devices. Keeping contact with external partners. Providing scientific coordination. Commissioned scientific responsible in internal projects, and R&D contracts.
- Deputy head of department; scientific expert of pharmaceutical development
Egis Pharmaceuticals PLC 2015-2016.
Responsibilities: scientific support activity, evaluation of product and process development ideas. Keeping contact with external partners. Controlling the application of project- and process management theories into the everyday life of EGIS. Providing scientific coordination. Commissioned scientific responsible in internal projects, and R&D contracts. Overseeing quality assurance processes.
- Senior development pharmacist
Egis Pharmaceuticals PLC 2009-2015.
Responsibilities: collecting experimental results from within the Company, as well as from CROs. Continuous monitoring of recent scientific literature. Preparing development plans, conducting and overseeing experimental work. Programming development tasks. Conducting experimental productions as well as the development of quality requirements. Controlling and overseeing the development tasks. Writing SOPs, participating in validation-, performance qualification- and other QA related tasks. Organizing the work of technical colleagues.
- Development pharmacist
Meditop Pharmaceuticals Co. Ltd. 2000-2009.
Responsibilities: DP development. Guiding DP production. Preparing, translating and controlling documentation for development, production and instrument use. Analytical work.
- Researcher
Semmelweis University, Budapest 2002-2009.

QUALIFICATIONS

- Advanced Design of Experiments for Product/Process Optimization 2022.
(BII World)
- Design of Experiments for Product/Process Optimization 2022.
(BII World)
- Authentic communication – management course 2022.
Szinergia Inc. (<https://www.szinergia.hu/>)
- Digital transformation 2018.
Kurt Academy Ltd. (<https://kurtakademia.hu>)
- Global Module 3 Chemistry & Pharmacy 2016.
A. Willis Consulting (<http://awillisconsulting.com/>)
- GMP – Fundamentals of Good Manufacturing Practice 2016.
University of Szeged, Faculty of Pharmacy, Department of Drug Regulatory Affairs
- Quality by Design – Making next generation process efficiency a reality for Chemical and Biotech Product Development and Optimisation 2015.
DIA Training Course
- Specialization in pharmaceutical technology 2008.
Semmelweis University Budapest

DEVELOPMENT HIGHLIGHTS

- Personal radiotoxicological unit set for the Hungarian Military (*Retarded, stabilized iodine salt tablets process for manufacturing of this and application for depleting the radioiodine contamination. Hungarian Patent P0105251, 2001.*)
- Nasopax nasal spray for adults and children.
- Explemed Rapid (Aripiprazole) 5 mg, 10 mg, 15 mg, 30 mg orodispersible tablets

SCHOLARSHIPS, FOREIGN EXPERIENCES

- 2008. June 3 month: Università degli Studi di Parma (Italian-Hungarian Intergovernmental S&T Cooperation Programme)
- 2006. June 2 weeks: Università degli Studi di Parma (Inter-University exchange programme)
- 1999. September 3 month: Università degli Studi di Milano (ERASMUS Scholarship)
- 1989. June 1 year: Washington Irving Intermediate High School, Springfield, VA, USA

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LANGUAGES

- Hungarian (native speaker)
- English (fluent)
- Italian (basic spoken)

AWARDS, PRIZES

- 2002. April Pharmacia Leonardo Award (Pharmacia Upjohn)
- 2002. March Mozsonyi Sándor Foundation, Application in Tutorial Category, "Microwave drying and kinetic investigation of solid systems with different dielectric properties" subject 1st prize
- 1998. April: Commendation of the Board of the University's Faculty

MEMBERSHIPS

- Hungarian Pharmaceutical Society, Organization of Industrial Pharmacy / president for 2 terms, member of the board, currently member of the Society
- Hungarian Chemical Society / former member

COMPUTER SKILLS & COMPETENCES

- Microsoft Office™ tools (Word, Excel, PowerPoint, Teams, SharePoint, MS Project),
- different DoE and QbD softwares (e.g. Statistica, JMP, MiniTab, QbD Works)
- assembly of hardware
- basic user of Corell™ and Photoshop™ graphical applications
- basic webpage editing knowledge

HOBBY, SPORT

skiing, tracking, photography, cooking

DRIVING LICENCE

B category