

Jürgen DOBMEYER

ER5, **Bionethos Innovation GmbH**, Germany

Postdoc Research Activities

February 2016

Exploration and assessment of the current national and European regulatory framework and optimization of the use of existing authorization and certification procedures for advanced therapy medicinal products or medical devices

Achievements so far

“Initially the focus of the project was research and training on regulatory procedures, review of available literature and publications including but not limited to pre-clinical and clinical data and manufacturing standards, benchmarks from other health care or pharmaceutical/cosmetic/medical device development activities. I have also reviewed and assessed different regulatory processes and current regulatory trends.”

Current and upcoming work

“An additional aspect of the future work is the identification of potential development and authorization/certifications risks but also opportunities. This will also include the development of risk minimization and mitigation strategies when selecting regulatory pathways. The future activities will also include the support of additional functional resources (laboratory, commercialization, clinical operations, science, manufacturing) to allow upscaling and transferability of processes and procedures using the regulatory expertise to ensure compliance with relevant national and international regulations and guidelines.”

The bigger Picture

“I feel that the future already started today: The option of an individualized therapeutic management, the promises of personalized medicine tailored to the genetic, epi-genetic and clinical background of each patient in combination with the development of companion diagnostics and complex medication delivery and administration technologies, the personalization of the manufacturing processes in a European market with >500 million of people... all this requires diligent regulatory control and careful oversight. Salus aegroti suprema lex: the safety and well-being of the patient is our highest goal. I am positive my work will deliver a piece to achieve these aspirations.”