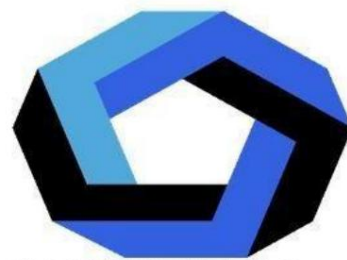




Activity and Areas of responsibility of the initiator Joachim Lugojan, dentist



**APOLLONIA –
JOACHIM LUGOJAN**
THE SOLUTION FOR A COMPLETE WORKFLOW



Areas of activity and responsibility of the initiator Joachim Lugojan, dentist

1. Development of the product vision

- Defining Apollonia's long-term vision and strategic goals
- Definition of the medical, dental and economic benefits • Determination of the intended user groups
- Definition of the planned areas of application
- Differentiation from practice management software, CAD/CAM systems and others
Dental platforms
- Prioritization of functions and development stages
- Further development of the business and revenue model

2. Professional leadership as a dentist

Mr. Lugojan brings the dental expertise that a purely software company lacks. cannot cover:

- Description of actual workflows in dental practices and dental laboratories
- Definition of the digital treatment steps
- Definition of medical and dental technical requirements
- Description of typical treatment and application cases
- Review of the results suggested by the software
- Assessment of clinical plausibility •
Definition of professional warnings and safety limits
- Coordination with dentists, dental technicians, orthodontists and others
experts
- Ensuring practical usability

3. Role as Product Owner

Mr. Lugojan acts as the central contact person for external development partners:

- Creation and explanation of the technical requirements catalog •
Translation of dental procedures into understandable software requirements
- Description of functions, user roles and process steps
- Prioritizing the product backlog •
Approval of user interfaces and workflows
- Participation in development and coordination meetings
- Answering technical questions from developers •
Evaluating interim results and prototypes
- Acceptance or rejection of delivered functions
- Documentation of change and addition requests
- Decision on the inclusion of new functions

4. Management of external partners

- Selection of suitable development, AI, cloud, data protection and regulatory partners •
Participation in the preparation of proposals and specifications
- Monitoring of scope of work, deadlines, milestones and costs
- Coordination of the various service providers
- Review of services rendered
- Monitoring of improvements and error corrections
- Release of invoices after successful performance verification
- Monitoring compliance with confidentiality and data protection regulations
- Ensuring that source code, documentation, usage rights and
- Work results are transferred to the Apollonia company in accordance with the contract.

5. Professional support for AI development

- Definition of suitable use cases for artificial intelligence • Determination of medically desired AI outputs • Selection and expert evaluation of suitable training and test data • Monitoring of data quality and representativeness • Labeling and expert classification of datasets • Verification of AI results for errors and clinical plausibility • Definition of threshold values and cases in which human decision-making remains necessary
- Documentation of potential errors in judgment and risks • Participation in preventing professional biases • Monitoring of AI performance during development and after market launch

External specialists can handle the technical development and training of the AI. However, the professional evaluation of the results should be carried out under dental supervision.

6. Tests, pilot projects and acceptance

- Development of realistic test cases • Organization of pilot practices and dental laboratories • Planning and support of practical tests • Collection and evaluation of user feedback • Testing of usability and process quality • Documentation of errors, risks, and suggestions for improvement • Definition of acceptance criteria • Conducting the final technical acceptance
- Decision on the release of individual development stages • Participation in the decision-making process regarding final market readiness

7. Medical Device Law and Regulatory Preparation Depending on the

legally defined purpose and functions, Apollonia could be classified, in whole or in part, as medical device software. The classification is the responsibility of the legal manufacturer; it cannot be completely delegated to the software company. This is also confirmed by the **BfArM (Federal Institute for Drugs and Medical Devices) regarding the classification and demarcation of medical devices.**

Mr. Lugojan should therefore contribute his expertise to:

- Definition of the medical purpose • Differentiation between medical and non-medical functions • Description of indications, users, and patient groups • Support with risk classification • Participation in the quality management system • Medical input for risk management • Assessment of foreseeable misuse • Support with clinical evaluation and performance evidence • Compilation of scientific literature and clinical findings • Review of the instructions for use and safety information • Support with technical documentation and CE conformity assessment • Collaboration with regulatory affairs advisors and, if necessary, a notified body

position

- Professional support for market monitoring after product launch

Important: Mr. Lugojan does not have to personally handle all the special regulatory tasks. Quality management, data protection, clinical evaluation, and regulatory support can be handled by qualified specialist companies. However, he provides the technical foundation and makes or confirms the key product decisions.

8. Data protection and IT security

- Determining which patient and treatment data are required
- Checking whether data collection is professionally necessary
- Contributing to data protection and authorization concepts
- Defining user roles and access rights
- Coordinating on pseudonymization or anonymization of data
- Supporting data protection impact assessments
- Contributing to the definition of storage and deletion periods
- Monitoring the professional requirements for data exports and interfaces
- Coordinating with data protection officers and IT security experts
- Contributing to the evaluation of security incidents

For medical devices, risks related to interfaces and cybersecurity must also be considered throughout the entire product lifecycle, as the **BfArM explains regarding the cybersecurity of medical devices** .

9. Building the professional network

- Recruiting dentists and dental laboratories as development partners
- Establishing a medical-dental technology advisory board
- Maintaining contact with universities, clinics, and research institutions
- Acquiring pilot users and reference customers
- Building collaborations with equipment and software manufacturers
- Involving professional associations and industry experts
- Participating in specialist events, congresses, and dental trade fairs

10. Financing and company setup

- Professional presentation of the project to investors, banks, and funding agencies
- Contribution to the business plan, financial plan, and pitch deck
- Explanation of market needs and unique selling proposition
- Participation in investor and financing meetings
- Support with grant applications
- Monitoring of the development budget
- Participation in the establishment of the Apollonia company
- Support in staff recruitment
- Strategic preparation for future internationalization

11. Preparing for market launch

- Defining product packages and target groups
- Contributing to pricing and licensing models
- Developing a professional sales pitch
- Creating and reviewing product descriptions
- Preparing training and demonstration materials
- Presenting the software to practices, laboratories, investors, and partners
- Training sales, support, and pilot customers
- Setting up a system for complaints and user feedback
- Providing professional support for the launch in Germany and later in other markets

Delineation of responsibilities

Mr. Lugojan / Apollonia

Product vision and strategy

Technical and clinical requirements; Technical implementation of the requirements

Prioritization of functions

Description of dental processes

Technical assessment of the AI

Definition of acceptance criteria

Technical inspection and approval

Selection and management of service providers; provision of the agreed services

Contacts with pilot practices and laboratories

Product and market decisions

External technology and development partners

Software architecture and programming

Effort estimation and development planning

Frontend, backend and database development

Technical development and training of AI

Conducting technical tests

Troubleshooting and technical documentation

Technical operation of the test systems

Technical consulting and implementation