Foundation Document – Persona "Quality Manager at Diagnostics Institute"

1 Work (Tasks, Workflows, Context)
- establish a quality management system that fulfils the legal/regulatory requirements
- keep the quality management system "alive" and in practical usage and work on continuous improvement of the quality management system (maintenance and elaboration of QM material, monitoring of the QM processes...)
- develop standardised processes and documents/forms (in close cooperation with the institutes' management and the quality managers of the departments)
- organise QM training for the team
- collect and assess performance indicators (as defined by the institute's management), and regularly report to the institute's management
- detect and document deviations and errors, and make suggestions for improvement
- contact person for external auditors
- contact person for the institute's staff, with regard to QM topics/issues/improvement suggestions
- create SOPs for verification/validation of new devices or processes (developing the study plan, as well as monitoring and documenting the study)

2 Education / Career
- scientific education (e.g. university study) in a field thematically related to the working area of the institute
- continuous further education (attending courses...)
- "learning by doing"
- career: start with QM for project, then successively work on larger QM tasks

3 Knowledge / Skills
- quality management knowledge
- technical knowledge in the working area of the institute
- communication skills, leadership skills, skills in team-building
- knowledge regarding statistics and experience in working with statistical analysis tools

4 Personal Traits
- patience and imperturbability
- stamina
- structured and organised
- willing to learn
- reliability
- self-conscious and assertive
- solution oriented
- empathic

5   Motivational Factors

- order and structure
- recognition for the QM work
- colleagues, who participate in the QM work
- QM work is supported by the institute's management
- QM is integrated part of the institute's work
- self-motivation by recognising the necessity of the QM work
- motivation doesn't come from work, but there are other motivations in life such as hobbies and family

6   Frustrations / Hurdles

- there are colleagues, who do not accept the QM
- lack of decisions at management level cause delay/stagnancy in QM processes
- if I cannot resist to be immersed in a problem/conflict
- missing support from institute's management
- it is hard to be the solely responsible for QM and having no QM team at the institute

7   Goals / Values

- successful certification/accreditation of the institute
- QM should be integrated into all processes at the institute
- it should become a natural habit of all staff of the institute to integrate QM into their daily work
- QM should be seen as a service and support for the whole institute
- all staff should recognise and understand the purpose and value of QM
- communication with the staff at the institute should be on a level playing field
- it is important to stay "cool" and calm, and take criticism, conflicts and problems not personally
- a good communication basis with the colleagues at the institute is the main asset of a quality manager

8   Attitudes towards AI

- CE certificate is important for medical software
- software must be used exactly according to its specification (e.g. only in the specified application area / use case, for which it has gotten the CE mark)
- head of the diagnostics institute, a pathologist, must assess the quality and the trustworthiness of the software results
- would ask colleagues from other pathology institutes about their practical experience at their institute with the specific software solution