Compliance Day – RAPS NL

Looking back on Compliance Day – RAPS NL: Learning together, seeing more clearly!
We look back with pride on our presentation and the organisation of **Compliance Day – RAPS NL**, in collaboration with the **Life Cooperative Working Group Compliance**. Lidia van Huizen, coordinator of the MDR Fast Lane Unit UMCG, presented the lessons learned within the UMCG. This was followed by further discussion per theme and the insights were brought together in a panel discussion. This day provided valuable insights into the challenges and opportunities surrounding **MDR in-house development (IH-MDs)** and appropriate quality management.

An important insight was the question: should patients know that an IH-MD has been used in their treatment? This directly touches on transparency, trust and correct claims in healthcare innovation. At the same time, it became clear that **ISO 9001 and ISO 13485** are developing further apart, which requires sharper choices in quality management. We want quality verification to take place at cluster or department level, while responsibilities around compliance, workflow and product development are not always clearly defined. The preparation of **Technical Product Documentation (TPD)** also remains complex, particularly when it comes to properly recording intended use, user and functional requirements, and determining a design freeze in a timely manner. After all, changes after this phase have a major impact on documentation and traceability.

In addition, areas of tension between **clinical research and healthcare innovation**, and between retrospective and prospective documentation, were discussed. Insufficiently detailed claims or market orientation can lead to risks in safety, performance and the substantiation of choices compared to commercial alternatives.

Finally, it was emphasised that the step from prototype to operational product is a big one, and that structural feedback (incident reports, surveys, EPD data) is essential to understanding actual performance in practice.

Compliance Day confirmed how important it is to continue learning together, clarifying processes and ensuring that innovation and patient safety go hand in hand. It was a valuable day that will help us take mature steps in MDR in-house development!