# Design and development (ISO 13485:2016 clause 7.3)

Christmas is coming and today is advent,

but Santa and his Elves are not ready yet.

Is the processes deemed sufficient and good,

or can anything be totally misunderstood?

Design Control is almost the trickiest part,

Santa and his Elves need to be talent and smart.

To ensure they don’t miss an important thing,

planning and execution is everything.

The elves prepare the final Design Review,

and discover they missed a little screw.

When the design input is 100 % reached

The product can soon be safely released.

Don’t forget the clause 4.2.3 in ISO13485,

and upload the Medical Device File on the drive.

# Management responsibility (ISO 13485:2016 clause 5)

The second of advent is coming up

have the Elves managed the IT-backup?

Santa is stressed and the deadlines fills his mind,

the final QMS-approval need to be signed.

His Company is a Legal Manufacture,

and they need sufficient infrastructure.

Quality objectives, regulations and software tool,

so the CEO has to be really cool,

engaged, available, committed and true,

to the QMS, Santa, Elves, Customer and You.

A management review is planned at the end of the year,

to ensure the processes are followed and everything is clear.

# Risk Management in Product realization (ISO 13485:2016 clause 7.1)

Managing risk plays an important role,

to improve the Company is in total control.

The Elves evaluate the hazards and risks in several ways,

and they need to work for seven days.

Exhausted and tired they really need a brake,

to celebrate the third of Advent with a Christmas cake.

They document and summarize the risks in a perfect file,

and continue with the requirements with a satisfied smile.

Requirements is compiled in the traceability matrix,

when can the CE-mark finally be affixed?

The report must be ready before Christmas week,

and shall prove the product is robust and not weak.

# Ongoing...

Internal Audit (ISO 13485:2016 clause 8.2.4)

​Internal audit requires the most competent team

as things are not always as they first seem.

Review the processes with a risk-based approach,

the auditor may need a really good coach.