# **Consultancy and Project management**

**Regulatory compliance** 

**IT and Automation** 

**Validation and test** 

**Engineering** 



## **Company presentation**

#### **Base data**

- Founded in 1989
- HQ in Kirke Værløse
- A/S in 2007
- 20 dedicated employees
- No BSB



Disse sikkerhedssko fik vores medarbejder udleveret som nye af kunden ved starten af en 14-dages opgave. 2 1/2 år senere sad konsulenten stadig hos kunden fordi det han leverede var i topklasse og opfyldte alle forventninger fra kunden. Det er nok unødvendigt at nævne at arbejdet foregik ved maskinen...



### **Company presentation**

# **Socpe of supply**



#### Documentation

- (Master) Validation Plans
- User Requirements Specifications
- Design- and Functional specifications
- Design Qualifications
- Standard Operating Procedures
- Structuring the documentation process
- Other QA documentation

#### Test and Implementation

- FAT/ SAT and acceptance test
- Installation Qualifications
- Operational and Performance Qualifications

## Development of company qualification templates

As per requirement from client/end users



### **Key expertice**



- Commissioning, Qualification and Validation
- IT and data integrity
- Validated data transfer
- Audit trail
- Short and long term data storage/archiving
- Automation, SCADA and PLC systems
- PLC solutions / programming/ code review
- Batch and recipe
- Process and mechanical engineers
- Design, design review, design documentation
- Compliance software (based on frameworks)
- Bespoke SW solutions
- Test execution
- Training

