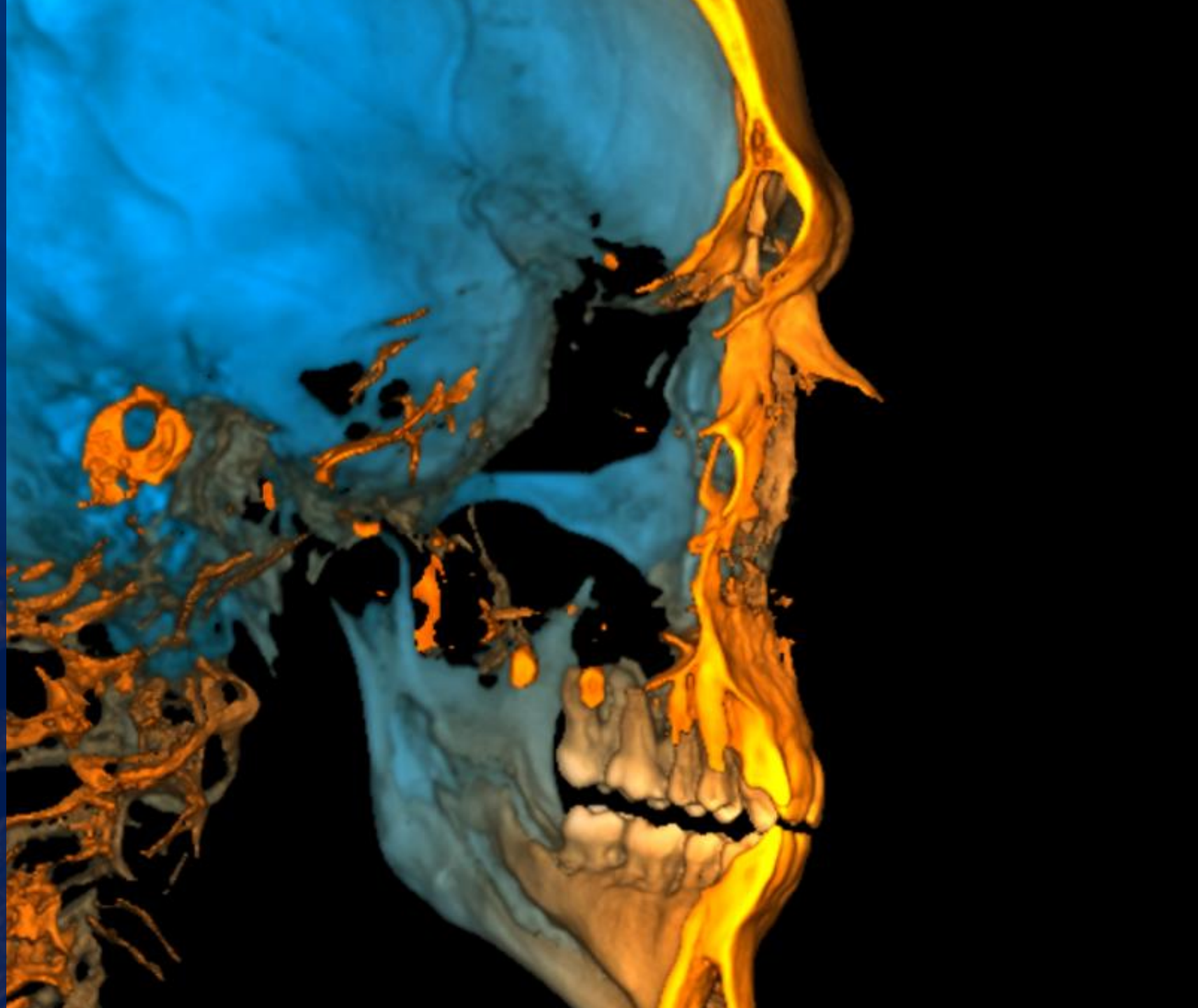


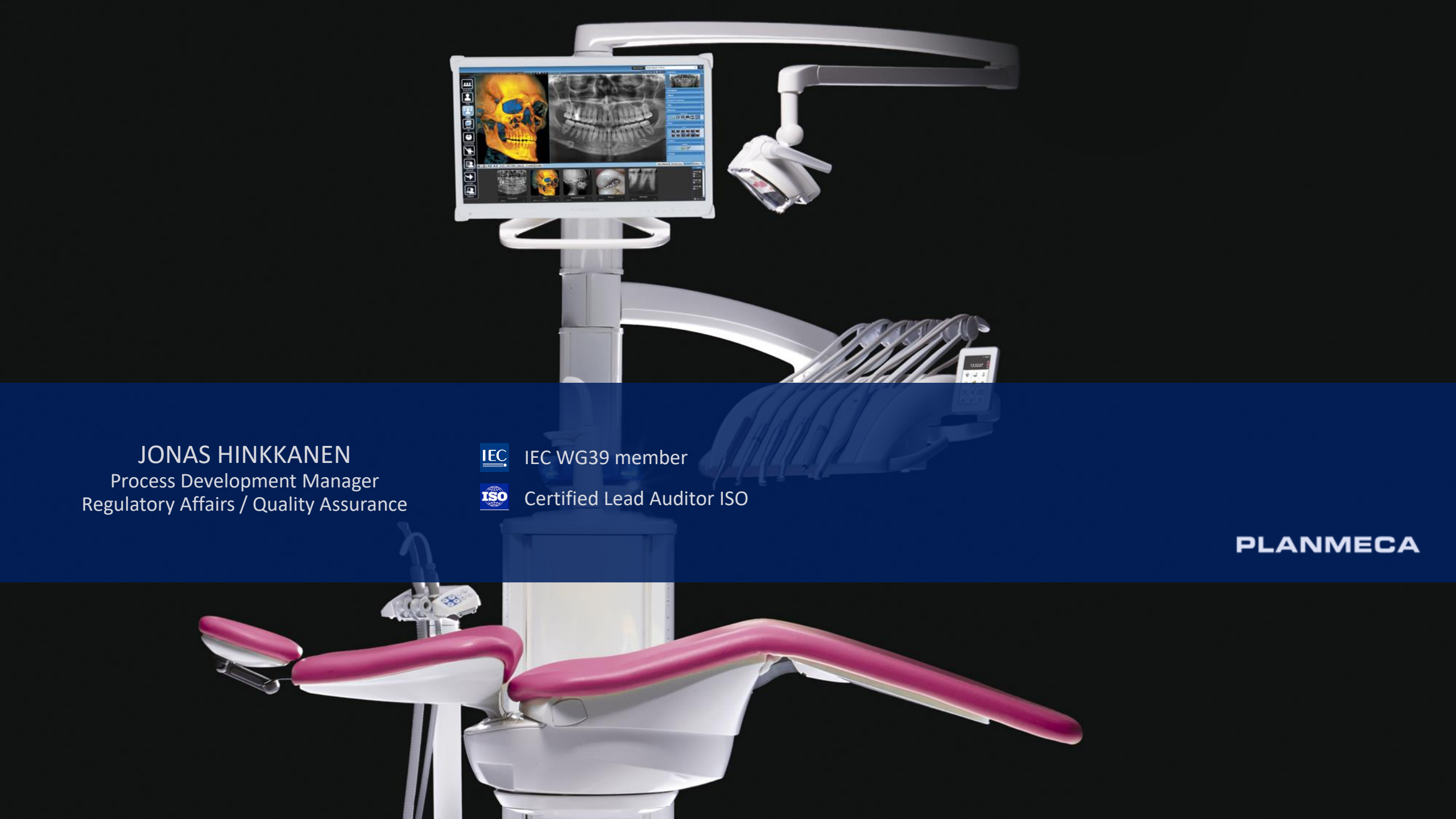
# PLANMECA

MEDICAL DEVICE RISK MANAGEMENT

POLARION BEST PRACTICES


Nordic Polarion User Day  
May 8, 2019





**JONAS HINKKANEN**  
Process Development Manager  
Regulatory Affairs / Quality Assurance

 IEC WG39 member

 Certified Lead Auditor ISO

**PLANMECA**



# What we do



Dental equipment,  
instruments and software



Dental supplies and services



Medical 2D and 3D imaging  
devices and software



Education



**2,800**  
**EMPLOYEES**  
WORLDWIDE

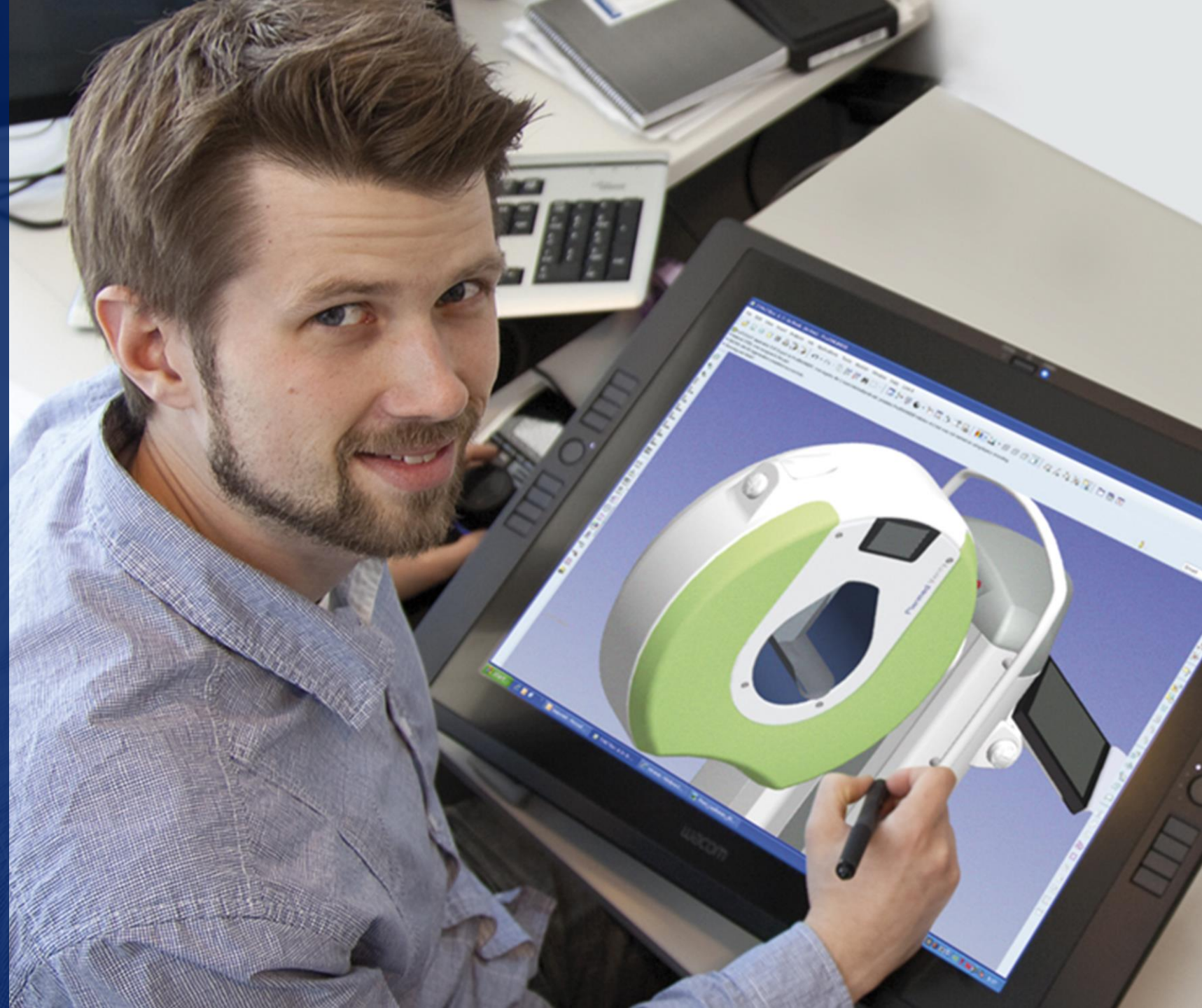


# Research & Development

In-house team of researchers and designers dedicated to emerging technologies

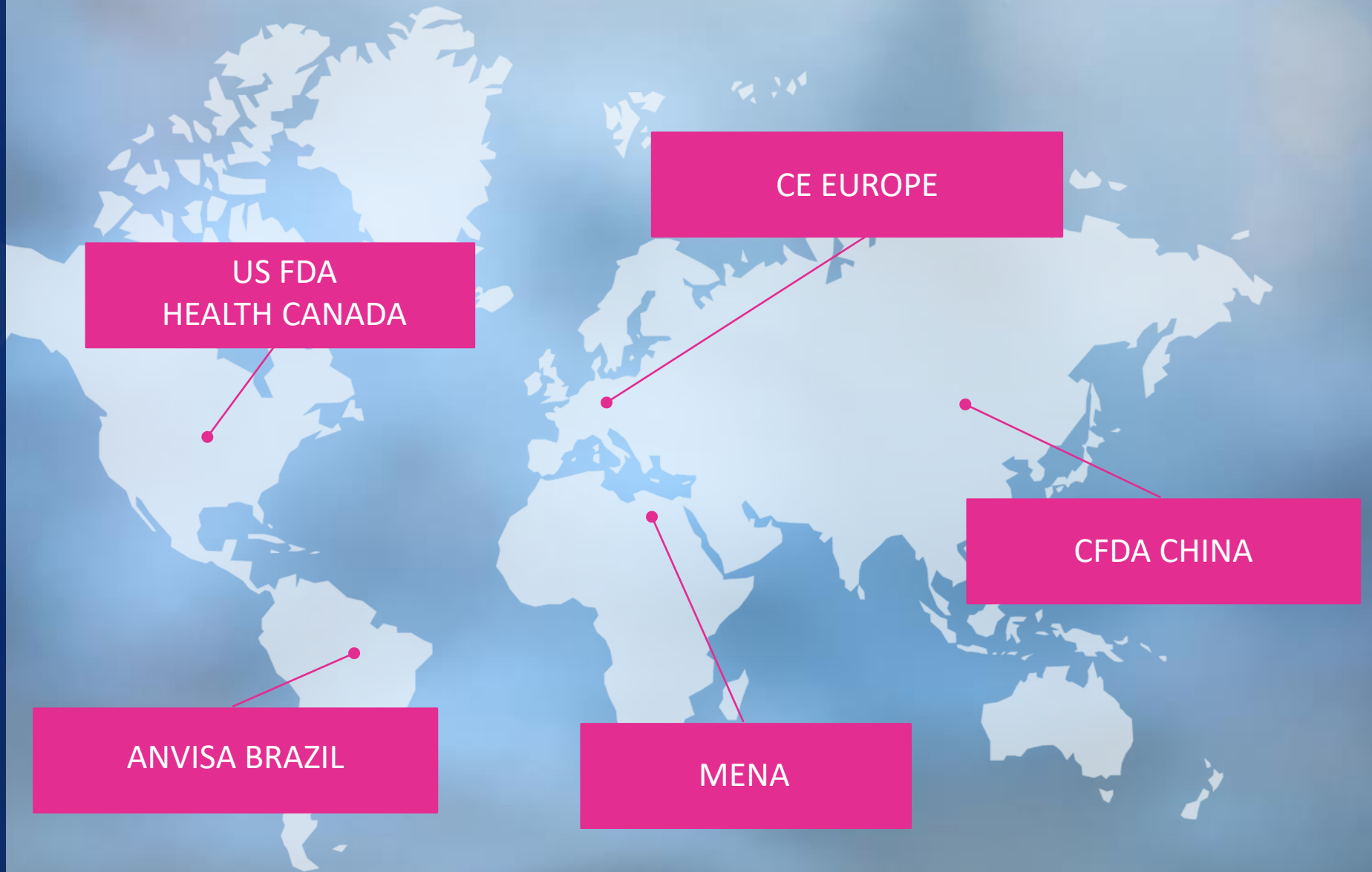
10 % of annual turnover goes to R&D

Over 400 global patents



# Regulated Industry

Globally over  
50 different submissions  
required



# Risk Management

Risk Analysis

Risk Evaluation

Risk Control

Residual Risk Evaluation

Verification

Validation

Risk Management Report



# Past

Excel, Word

PLANMECA OY



SUPER ASSISTANT



PLANMECA OY  
HELSINKI / FINNLAND

P<sub>M</sub> MODULAR  
SYSTEM





# Challenge of Complexity

Electricity, water, x-ray, mechanics,  
software

IoT, 3D materials

Change control



# Polarion ALM

Visibility

Collaboration and Team Work

Work Flows

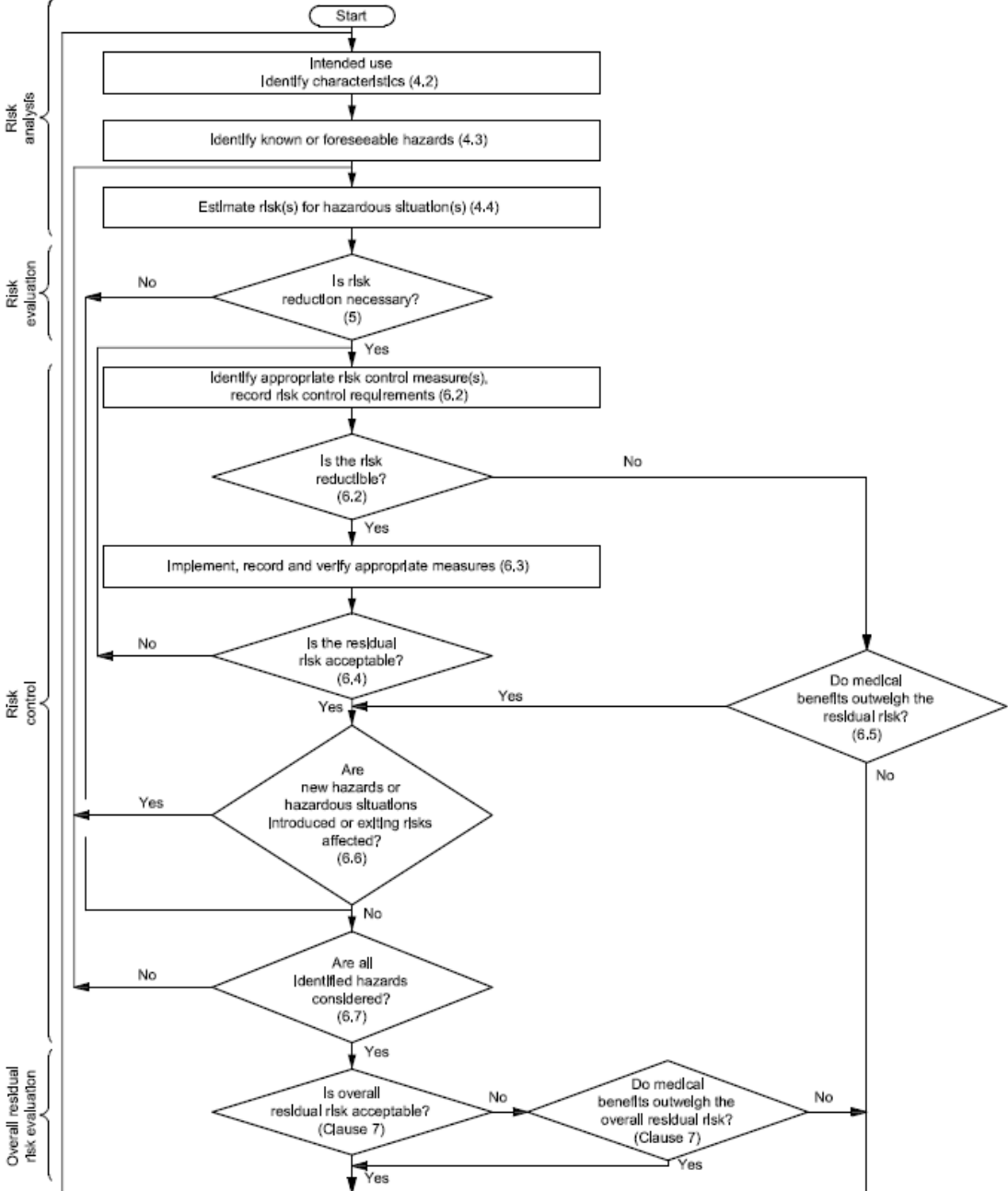
LiveDoc

Electronic signatures



# Lessons Learned

Define the process



# Lessons Learned

Define the process

Adjust Polarion to support the process

**Risk analysis**

Potential causes of leading to hazardous situation (SW): **Failure or unexpected results from SOUP**

Operating conditions: **Single fault condition**

Hazardous situation description: **Calculation algorithm halts**

Harm: **Negligible – inconvenience or self-recovery of device**

Subject to harm: **Operator, user**

Reference to Chapter of IEC60601-1 series, or other relevant standard:

Functional area: **Romexis Client**

**Risk evaluation**

Probability of hazardous situation occurring (P1): **Frequent**

Probability of hazardous situation leading to harm (P2): **Frequent**

Severity of harm: **Catastrophic**

Result of risk evaluation: **✘ Not accepted**

Software safety classification: **B**

**Risk Control Form**

TARGET:	RM2019-7 - Input power 230VAC (✓ Approved)
RISK V & V	RM2019-8 - Test double insulation (👉 Draft)

**Risk control**

Risk control option analysis: **Inherent safety by design**

Risk control description: **Recovery module is called**

Design group responsible of implementation: **Software**

SW mitigation design option: **Redundancy**

Implementation of risk control measures: **Shall be implemented**

Verification of risk control measures: **Recovery shall be tested**

**Residual risk analysis**

Probability of hazardous situation occurring (P1 residual): **Improbable**

Probability of hazardous situation leading to harm (P2 residual): **Improbable**

Severity of harm (residual): **Minor**

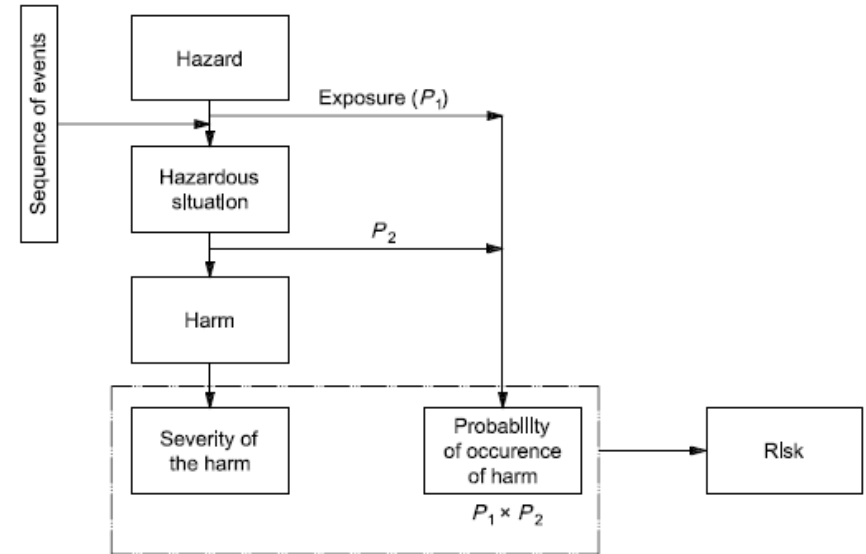
Result of risk evaluation (residual): **✓ Accepted**

# Lessons Learned

Define the process

Adjust Polarion to support the process

Do on-the-fly calculation



# Lessons Learned

Define the process

Adjust Polarion to support the process

Do on-the-fly calculation

Do on-the-fly judgement

## Risk evaluation

Probability of hazardous situation occurring (P1): **Frequent**

Probability of hazardous situation leading to harm (P2): **Frequent**

Severity of harm: **Catastrophic**

Result of risk evaluation: **✗ Not accepted**

Software safety classification: **B**

# Lessons Learned

Define the process

Adjust Polarion to support the process

Do on-the-fly calculation

Do on-the-fly judgement

Guide and steer the user as much as possible



## Actions required

### **Action required.**

*Hazardous situation description must be entered because of v:*



## Risk Control Form

### **Risk reduction not required.**

*Result of Risk level is  Accepted.  
No need to continue to Risk Control actions below.*

# Lessons Learned

Define the process

Adjust Polarion to support the process

Do on-the-fly calculation

Do on-the-fly judgement


Guide and steer the user as much as possible

Re-use and visualize information

Indicate statuses of related work items



## Risk Control Form

TARGET:	 RM2019-7 - Input power 230VAC (✓ Approved)
RISK V & V	 RM2019-8 - Test double insulation (✎ Draft)



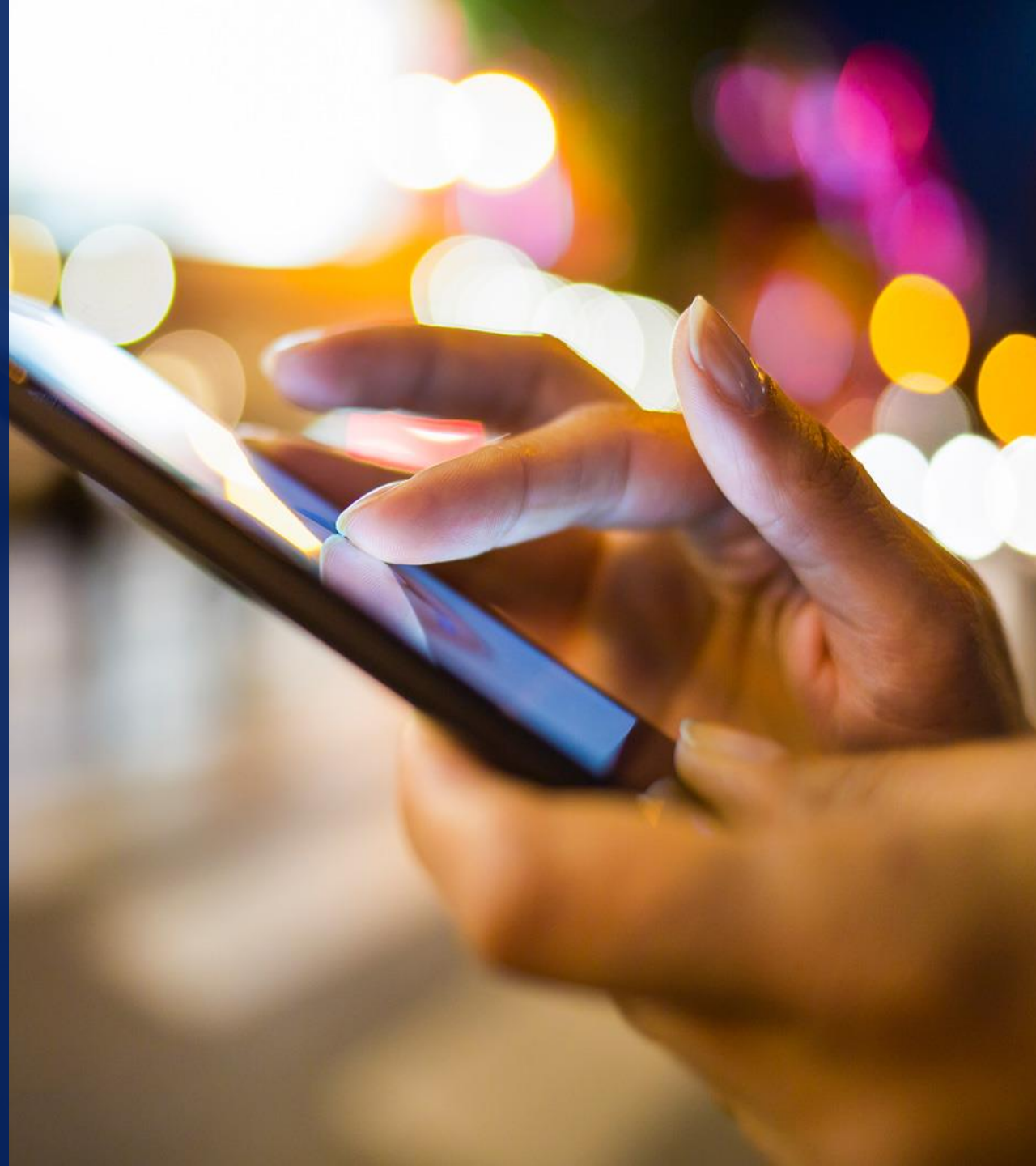
# How it has been done

## **ScriptFields**

extension using JavaScript  
used in calculations  
loaded at save

## **VelocityForm**

extension using Velocity scripting  
used in rendering of guidance  
dynamically loaded



**PLANMECA**

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