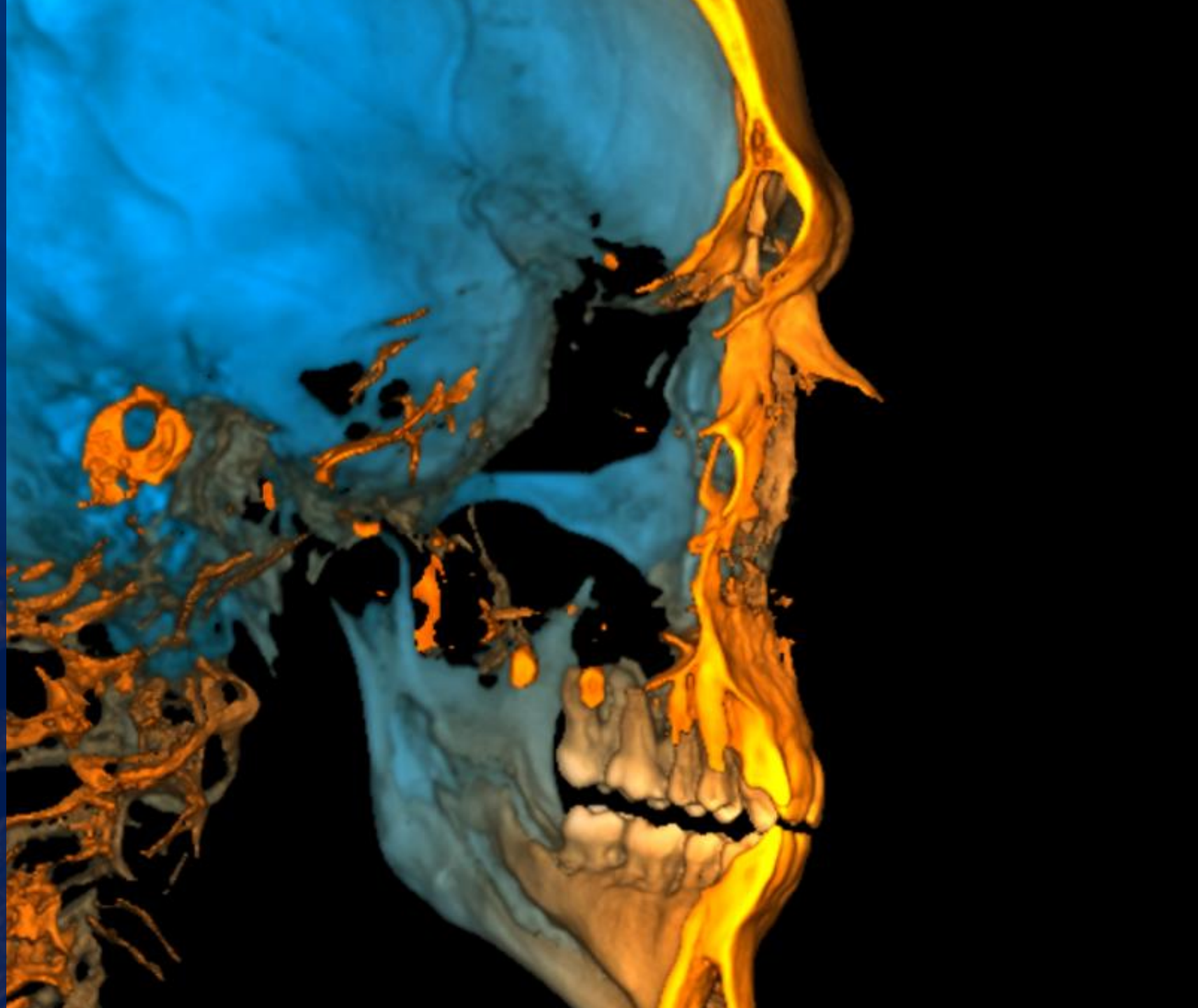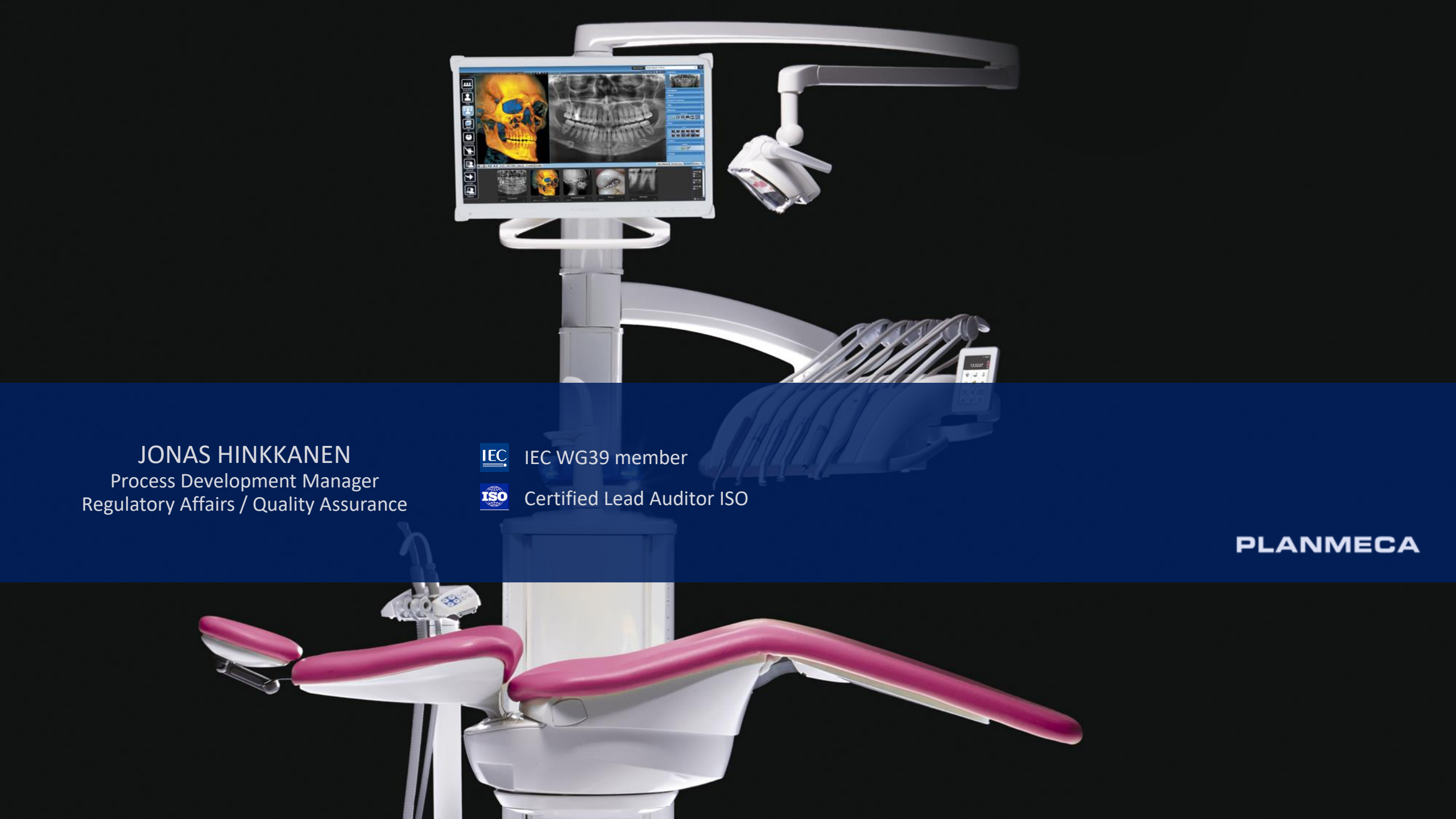# PLANMECA

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

98% OF PRODUCTS
EXPORTED
AROUND THE WORLD

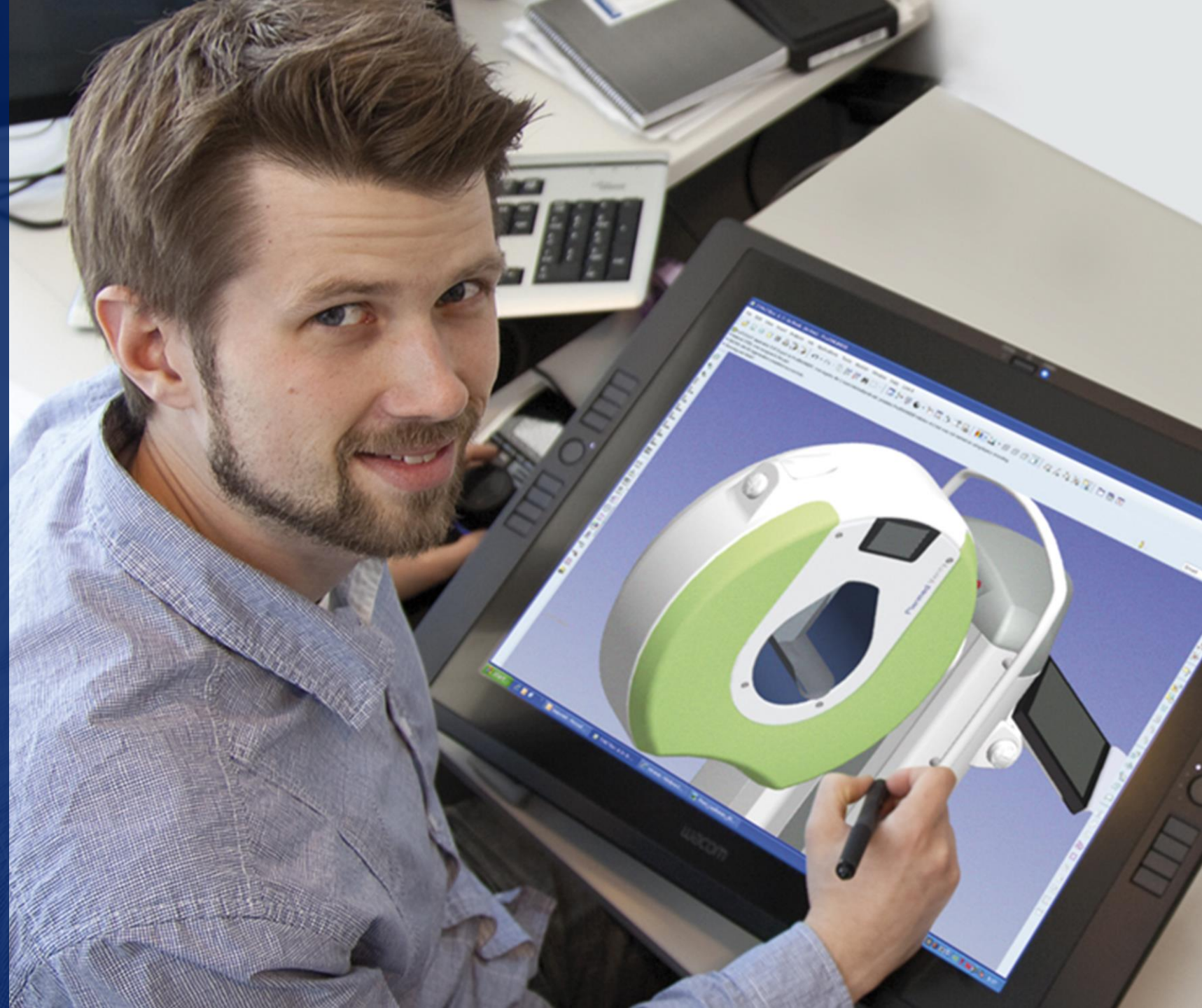**100,000**
SHIPMENTS
PER YEAR FROM HELSINKI

Research & Development

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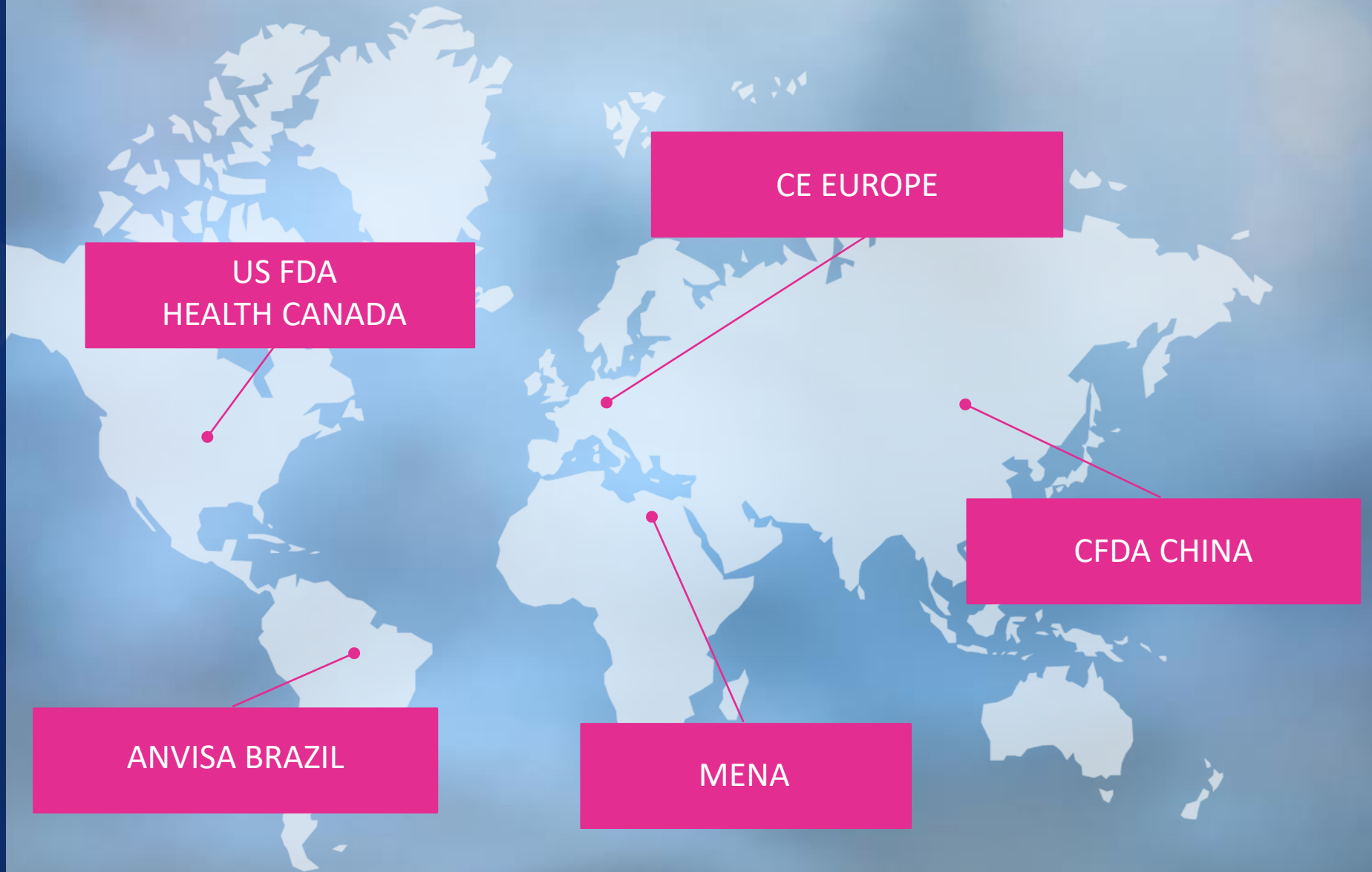and designers dedicated
to emerging technologies

10 % of annual turnover goes to R&D

Over 400 global patents

Regulated Industry

Globally over
50 different submissions
required

US FDA
HEALTH CANADA

CE EUROPE

CFDA CHINA

ANVISA BRAZIL

MENA

Risk Management

Risk Analysis

Risk Evaluation

Risk Control

Residual Risk Evaluation

Verification

Validation

Risk Management Report

Past

Excel, Word

Challenge of Complexity

Electricity, water, x-ray, mechanics, software

IoT, 3D materials

Change control

Polarion ALM

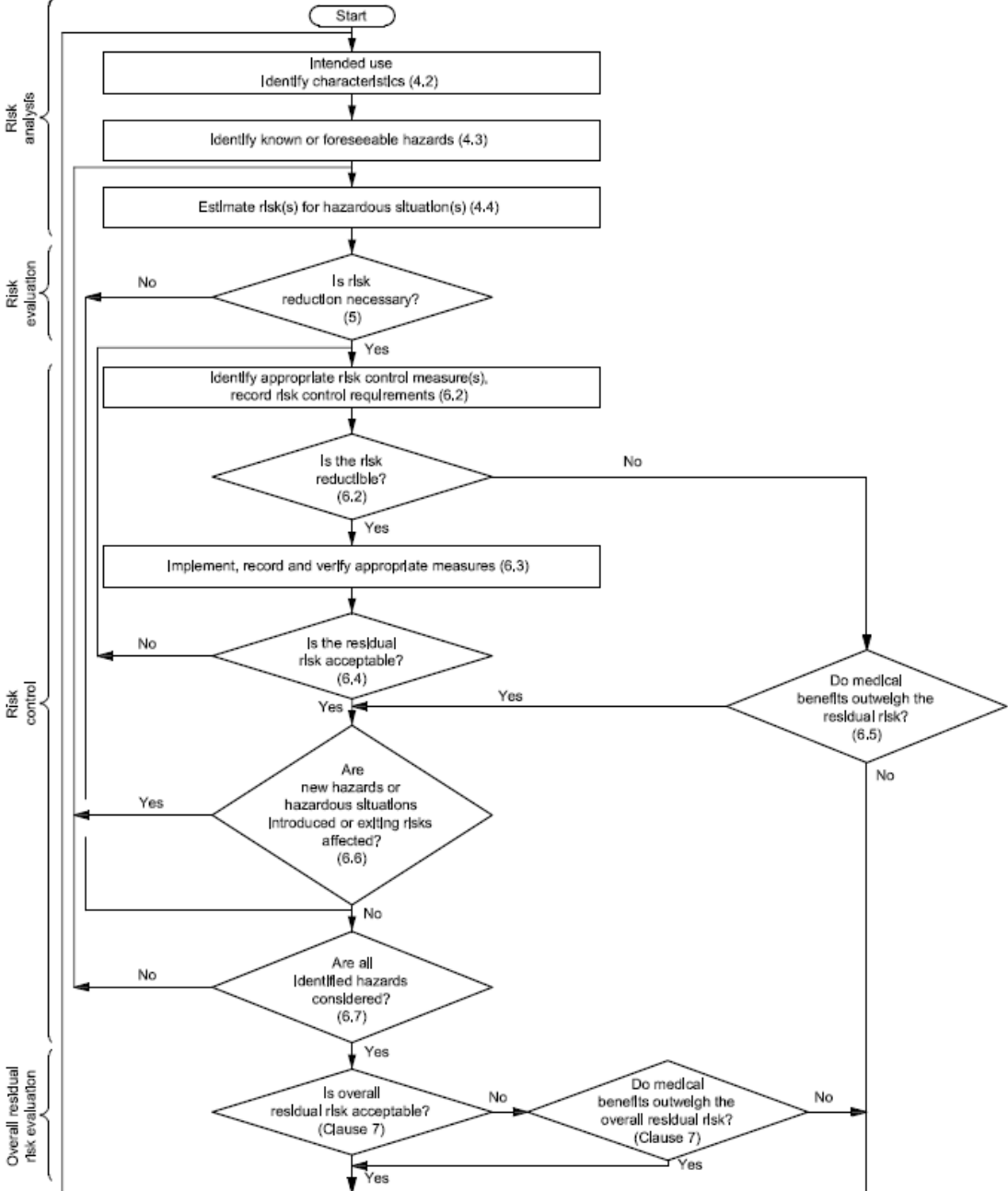Visibility

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

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 va

⚙ **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

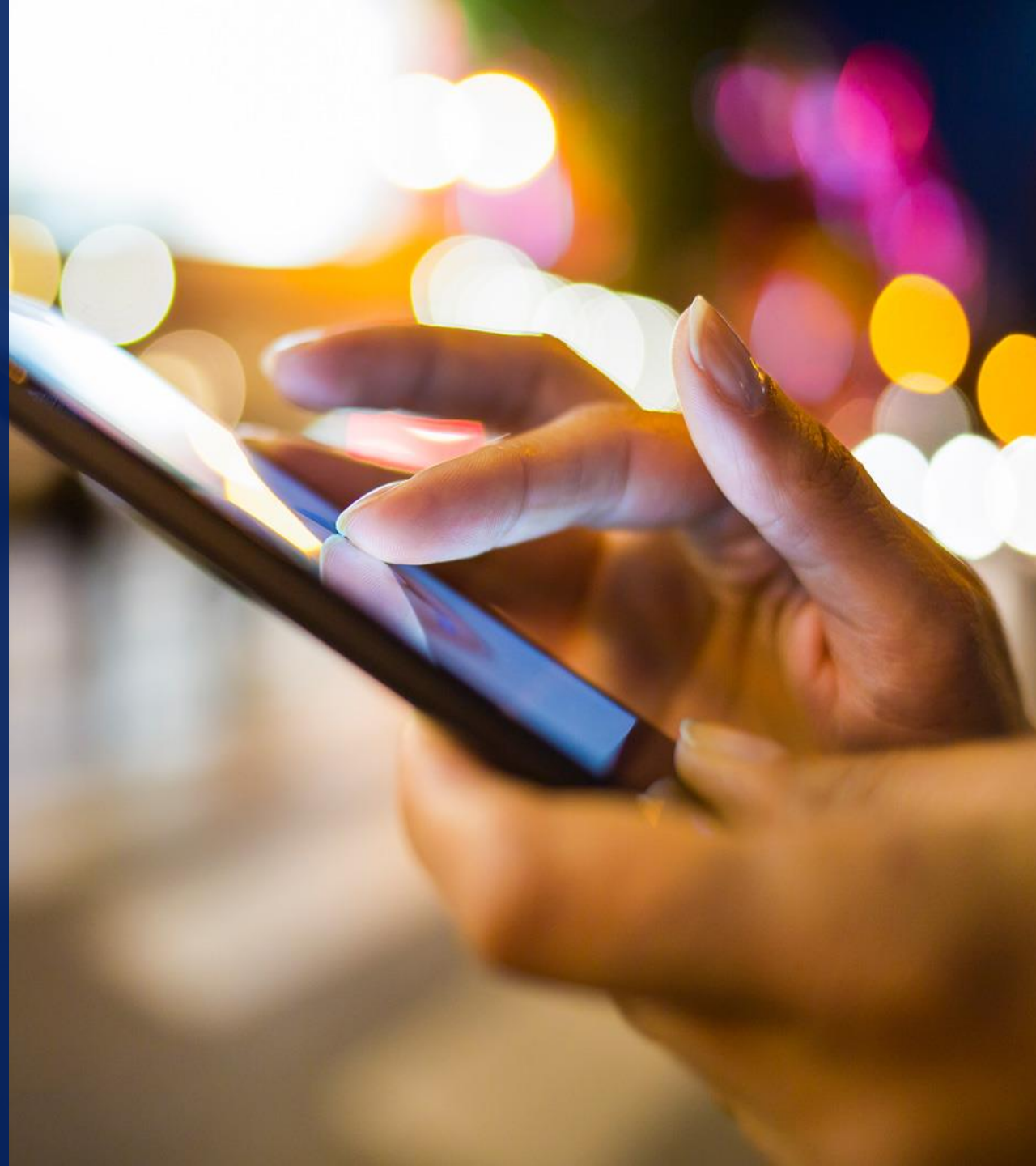Re-use and visualize information

Indicate statuses of related work items

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

taipuva

PLANMECA

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