

WORKSHOP 3

Accelerated framework for AI Compliance in Less Than an Hour!



Kenn Milton
CEO and Founder
MyBlueLabel

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INTELLIGENT HEALTH 2023

WORKSHOP 3: ACCELERATED FRAMEWORK FOR AI COMPLIANCE... IN LESS THAN AN HOUR!

MYBLUELABEL

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A person is working on a laptop, with their hands visible on the keyboard. The laptop screen displays a document with a circular diagram. The entire image is covered with a semi-transparent blue overlay.

MYBLUELABEL

MYBLUELABEL IN BRIEF



A SUBSCRIPTION-BASED SOFTWARE-AS-A-SERVICE COMPANY PROVIDING ACCESS TO A PROPRIETARY ELECTRONIC QMS PLATFORM AND COMPLIANCE KNOW-HOW FOR LIFE SCIENCE COMPANIES

FOUNDED
IN
2018

COMMERCIALISATION
STARTED IN
2021

HEADQUARTERS
IN
HØRSHOLM (DK)

NUMBER OF
EMPLOYEES
25

NUMBER OF
CUSTOMERS
270

REVENUE
2022/23 (DKK)
5.068.311

5.068.311 DKK (REVENUE)
= 679.716 EUR
= 651.510 CHF

THE WHY OF MYBLUELABEL



FOUNDER'S STORY



"BASED ON MY 20 YEARS' EXPERIENCE WITHIN QUALITY MANAGEMENT AND QUALITY ASSURANCE, I WAS INCREASINGLY PUZZLED BY THE **ABSENCE OF STANDARDISATION AND EFFICIENCY** IN THE IMPLEMENTATION OF REGULATORY FRAMEWORKS.

INSTEAD OF 'FIXING' COMPLIANCE FOR INDIVIDUAL CUSTOMERS AND ISOLATED PROJECTS, I WAS **LOOKING FOR STANDARDISATION, SCALABILITY AND A SOLUTION THAT WOULD BE ACCESSIBLE FOR ALL.**

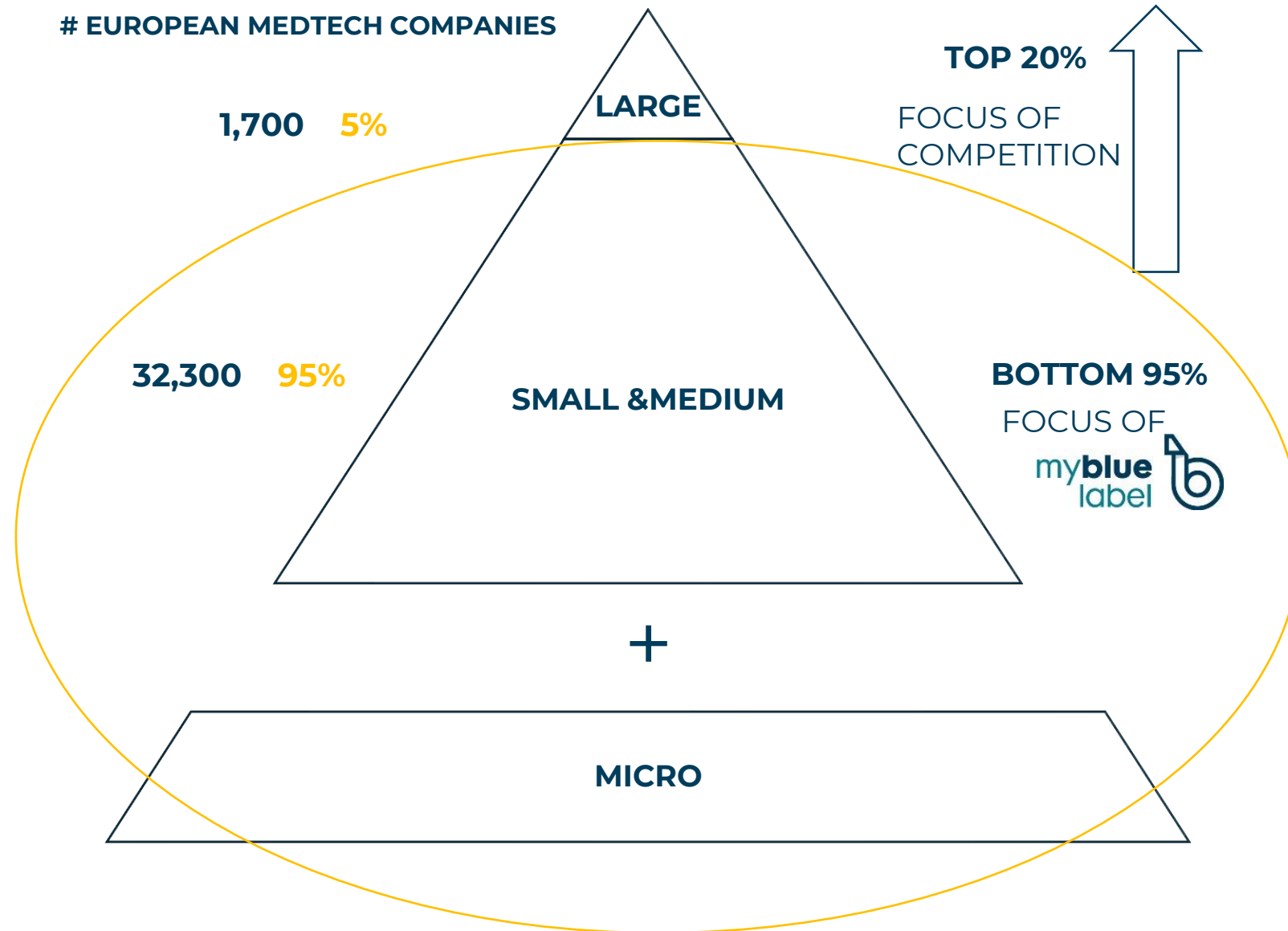
THAT IS THE REASON WHY I CREATED MY**BLUE**LABEL"

KENN MILTON, FOUNDER & CEO

FIRST-HAND EXPERIENCE FROM:



THE EUROPEAN MEDTECH MARKET



SOURCES:

[HTTPS://WWW.MEDTECHEUROPE.ORG/WP-CONTENT/UPLOADS/2022/09/THE-EUROPEAN-MEDICAL-TECHNOLOGY-INDUSTRY-IN-FIGURES-2022.PDF](https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf)

[HTTPS://WWW.STATISTA.COM/OUTLOOK/HMO/MEDICAL-TECHNOLOGY/MEDICAL-DEVICES/EUROPE](https://www.statista.com/outlook/hmo/medical-technology/medical-devices/europe)

OUR VALUE PROPOSITION



WHEN A COMPANY PLANS TO PLACE PRODUCTS ON THE MARKET, IT NEEDS TO CREATE DOCUMENTED OBJECTIVE EVIDENCE, THAT THE PRODUCT IS SAFE AND PERFORM AS INTENDED IN LINE WITH CE AND FDA REQUIREMENTS. **MYBLUELABEL OFFERS AN EASY, COST-EFFECTIVE AND FAST ROUTE TO COMPLIANCE AND EARLY MARKET ENTRY.**

THE TRADITIONAL WAY

1. DO IT YOURSELF
2. PAY CONSULTANTS TO DEVELOP TEMPLATES AND DOCUMENTATION
3. MANUAL UPDATES TO DOCUMENTS WHEN REGULATION CHANGES
4. TIMECONSUMING ANNUAL AUDIT

-
- **COSTLY** (COST TO IMPLEMENT DKK 2-3M)
 - **LONG TIME** TO IMPLEMENT (1-2 YEARS)
 - LIFETIME SPEND **DKK ~10M**

THE MYBLUELABEL WAY

1. ALL STANDARD TEMPLATES AND OPERATING PROCEDURES ARE AVAILABLE ON PLATFORM
2. MYBLUELABEL ENSURES UPDATES TO ALL DOCUMENTS WHEN REGULATION CHANGES
3. SIMPLE AND WELL-DOCUMENTED ANNUAL AUDIT

-
- **LOW COST** (COST TO IMPLEMENT DKK 50.000)
 - **SHORT TIME** TO IMPLEMENT (<1 MONTH)
 - LIFETIME SPEND **DKK ~1M**

WHAT THE CLIENTS SAY



“WITHIN JUST 5 DAYS WE HAVE A FULLY FUNCTIONAL QMS AND AN INTUITIVE IT PLATFORM TO SUPPORT OUR REPORTING – AT A FRACTION OF THE COST. IT LOOKS LIKE MYBLUELABEL IS DISRUPTING THE REGULATORY INDUSTRY!”

- SØREN H. DAM, CO-FOUNDER & CTO

READ MORE ABOUT VENOMAID DIAGNOSTICS [HERE](#).



CLIENTS & PARTNERSHIPS



CLIENTS
270

PLATFORM CLIENTS
151



SELECTED CLIENTS



SELECTED PARTNERSHIPS (EARLY EXPOSURE AND ACCESS TO MEDTECH & COMPLIANCE SPECIALISTS)



Nordic Health Lab ⊕



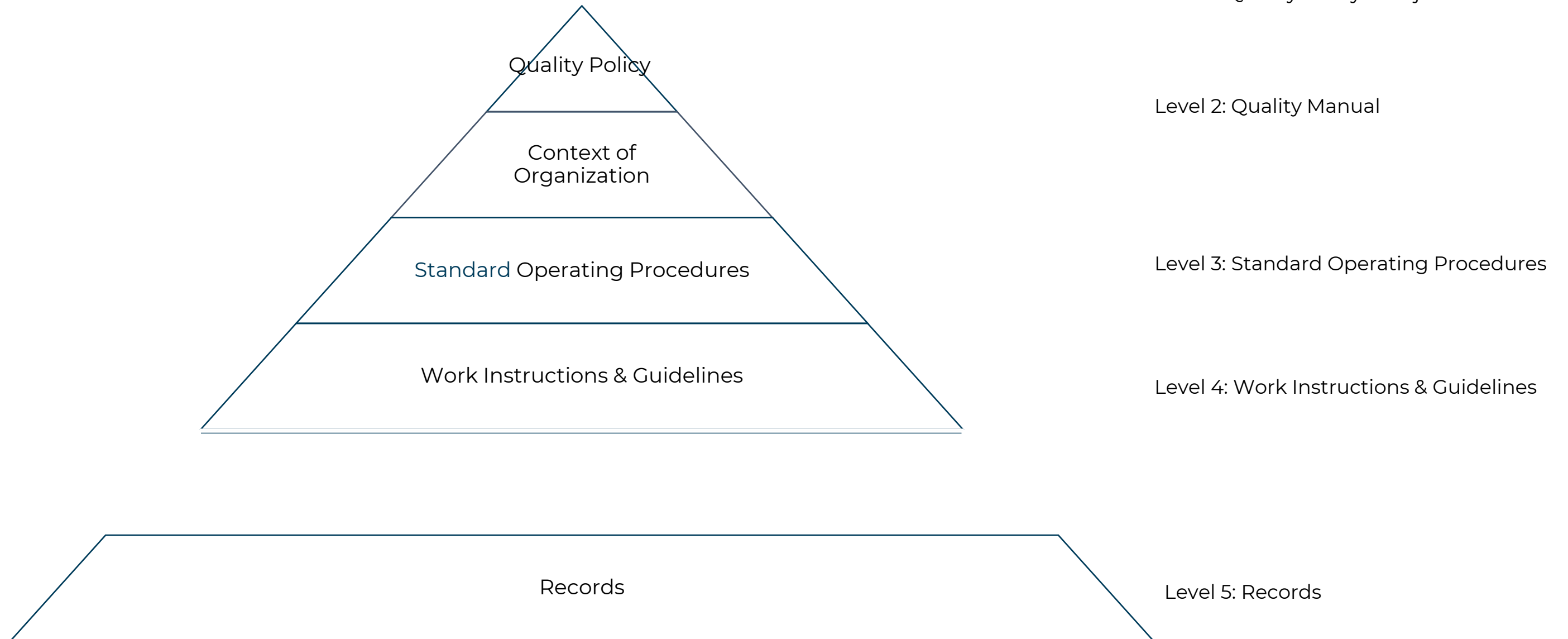
BioMedical Design
Novo Nordisk Foundation
Fellowship Programme



A photograph of a person's hands typing on a laptop keyboard, overlaid with a semi-transparent blue filter. The laptop screen displays a document with a pie chart and some text. The word "EXPECTATIONS" is written in large, white, sans-serif capital letters across the center of the image.

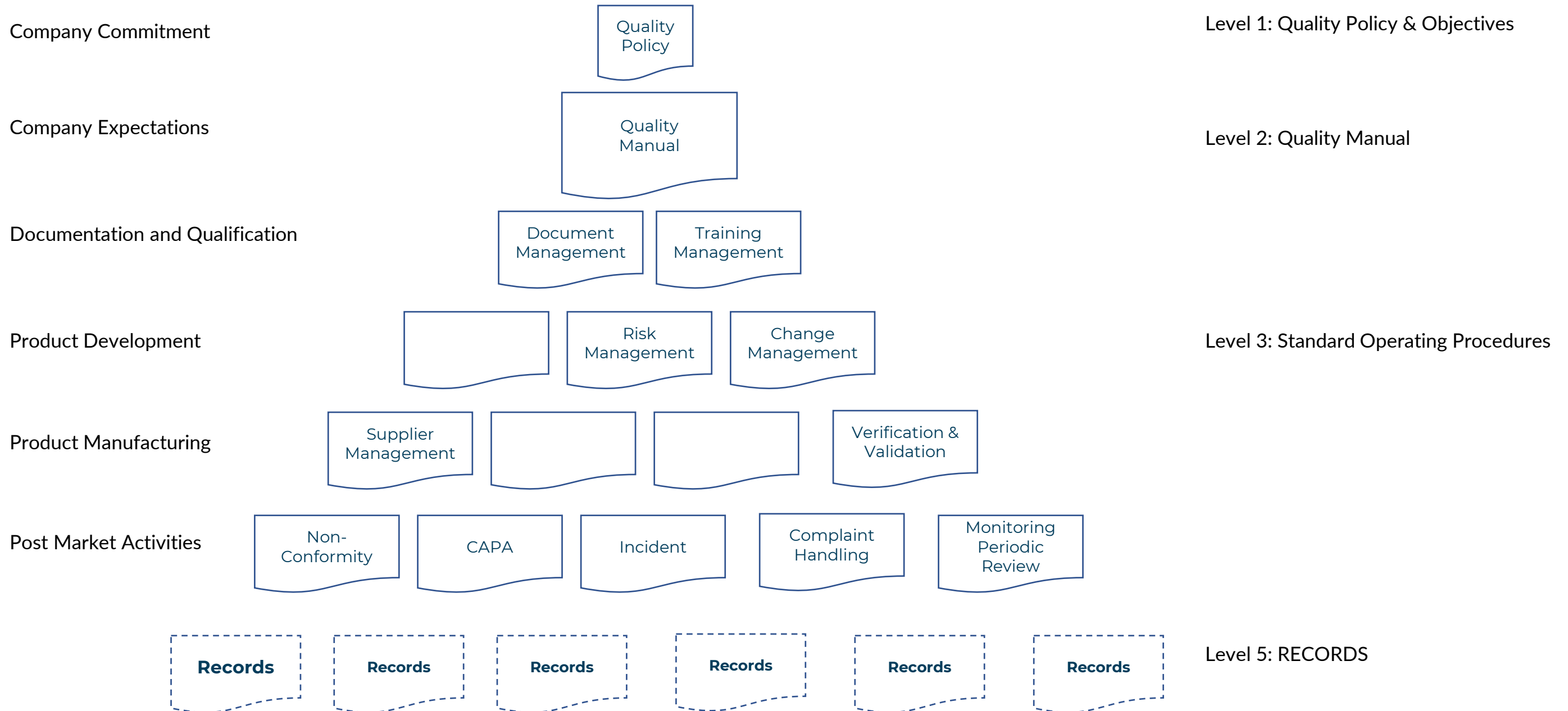
EXPECTATIONS

INFORMATION SECURITY MANAGEMENT SYSTEM



Triangle = Symbol of Power and Stability

POLICIES, MANUAL, SOPS, WI



Level 1: Quality Policy & Objectives

Level 2: Quality Manual

Level 3: Standard Operating Procedures

Level 5: RECORDS

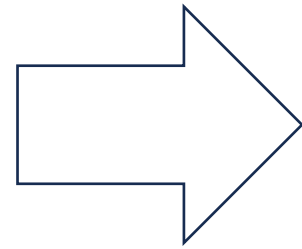
AUDITS

A person's hands are visible typing on a laptop keyboard. The laptop screen displays a financial dashboard with a pie chart and a bar chart. The entire image is overlaid with a semi-transparent blue filter.

AUDIT AND CERTIFICATIONS

STAGE 1

QUALITY POLICY & OBJECTIVES
CONTEXT OF ORGANIZATION
STANDARD OPERATING PROCEDURES



3 MONTHS

STAGE 2

QUALITY POLICY & OBJECTIVES
CONTEXT OF ORGANIZATION
STANDARD OPERATING PROCEDURES

RECORDS

MYBLUELABEL

MAKE COMPLIANCE A **LIFESTYLE**

MyBlueLabel Compliance Services ApS

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myblue
label