



COMPANY PRESENTATION

Stage One Computing A/S
[SOC], founded in 1987.

20 employees, each with a
very different background.

Stage One Computing A/S
Lejrvej 17
DK-3500 Værløse

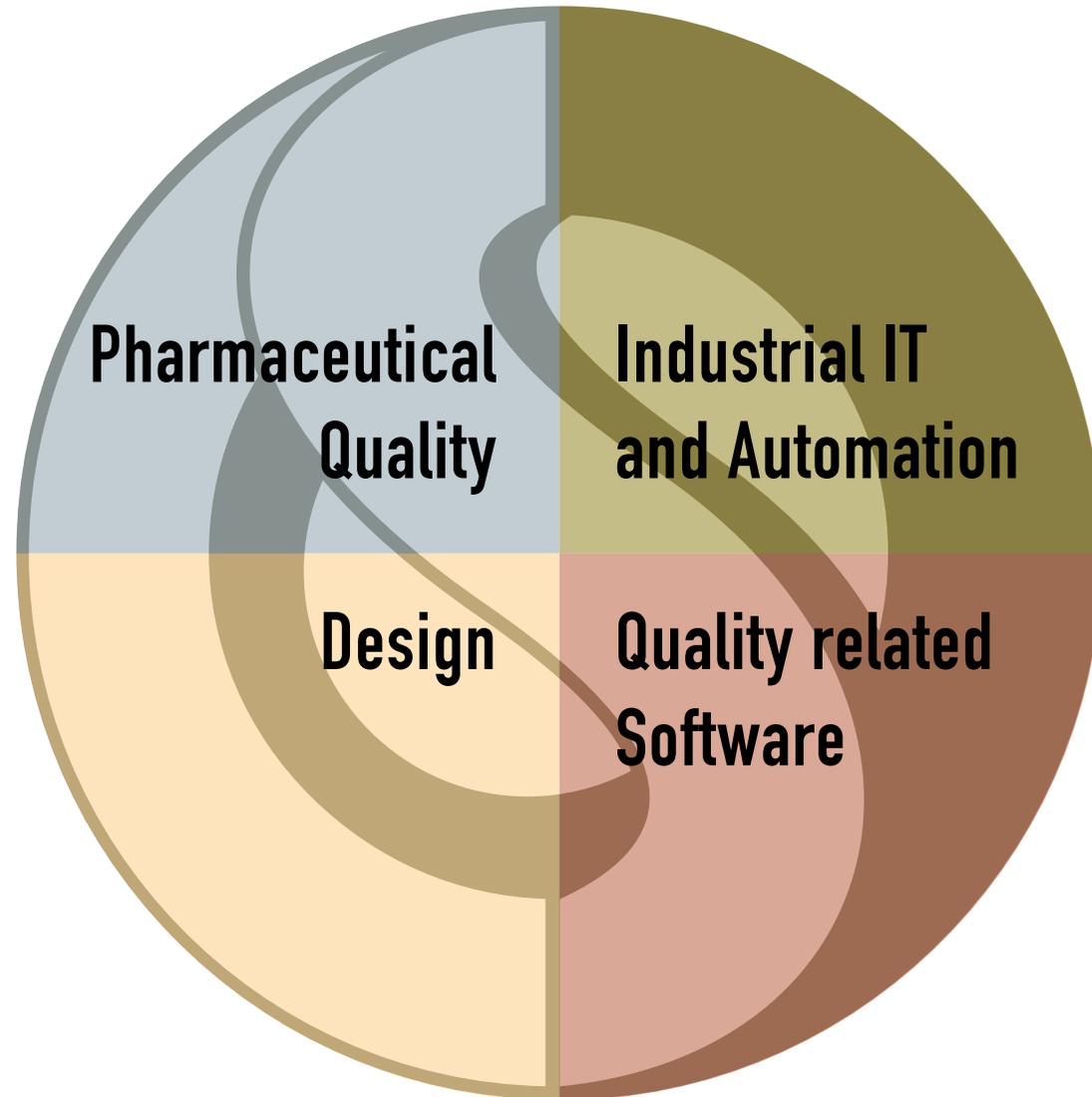
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CVR-nr 32943071

QA
Knowledge
Consultancy
Project Management
Engineering
Products
GMP



Pillars of Stage One Computing A/S at a glance



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Pharmaceutical Quality

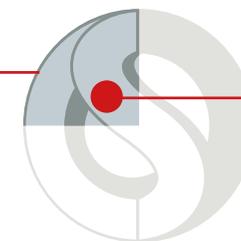
We have worked with pharmaceutical quality since the start of the 90'ties, and know our way around.

Primary goals are to maintain an operative state, by having an effective and clean quality system setup. If you can't explain a validation setup via a single simple drawing on a whiteboard, you are usually creating too much documentation or having unnecessary complex workflows.

We can support the entire range of pharmaceutical quality documentation from the requirement specification to the final process validation and operational procedures.

We also supply tailored training within validation and pharmaceutical quality concepts, automation and IT.

We have experts within most pharmaceutical processes, such as general IT, API production (process equipment), washing, autoclaves, CIP, mixing, filling, tableting, assembly, packaging and device production (hardware and software). We can provide a team of experienced testers within most of these fields within very short notice.



! We can support the entire range of pharmaceutical quality documentation...

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Industrial IT and Automation

Coming from the IT - and automation business, we still supply IT and Automation solutions.

- We have automation programmers within SattLine, Siemens, Allen-Bradley and DeltaV/Syncade.
- We can support various MES systems, such as PAS-X and SAP.
- We provide design of secure and robust networks.
- We support Windows and Linux platform design.

Currently our cyber security services are especially sought after, where we can provide protocol based security scan of Windows and Linux based systems, in order to provide a higher standard of IT security. Especially production equipment is in scope for securing data integrity.

We also provide **system integration between machines and company domains, so that machines can be centrally managed**, using Active Directory, uniform credentials and centralized system management with anti-virus, system health monitoring and centralized review of audit trails.



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Quality related Software

Stage One has developed a number of software components and applications, mainly for the pharmaceutical industry. It is our objective to **achieve true compliance at a significantly lower cost** through intelligent use of record based information. We develop applications and software for our customers, but also our own software products.

Our applications are used for optimization of processes, and to ensure that less errors are introduced in the quality process.

- SOCureLink** For ensuring linked data are available
- SOCPDFTool** Virtual PDF to PDF/A, embedded files and sign. to replace QC printers
- SOCanalytic** Automatic analysis of contents of written documents
- SOCopy** Valid data transfer within a network
- SOCWeld** Digital weld log
- SOCheck** Automatic rule based audit trail analysis

All our solutions offers full data integrity, and complies to data related regulations such as 21 CFR Part 11 and EudraLex vol. 4 annex 11.

Our applications are our own inventions, but developed in cooperation with our customers.



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Design

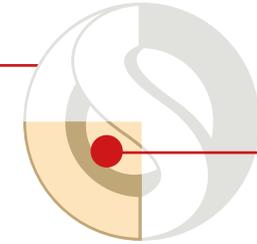
In our capacity as consultants we have participated in the design of factories, machines, systems or devices. Thinking carefully and defining the solutions will in our minds provide:

- **Less maintenance**
- **Ease of use**
- **Fewer deviations**

In total – better design gives less operational costs and less down-time of any system.

Our experience with good design comes from working in the pharmaceutical industry for over two decades. We strongly recommend to spend more time in the design phase, in order to minimize time spent later, on fixing problems which could have been caught earlier in the process. **Device development focuses on design qualification, and a good design history**, in order to more easily learn from earlier development lessons. This can easily be adopted to other areas within the industry.

A proper design is the best way of achieving a timely goal at a reasonable cost, and top quality.



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