
 **QIAGEN**

The Role of Systems Engineering in the GeneReader NGS System

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QIAGEN at a Glance

Customer Classes

Percentage share of net sales*

Customer Class	Percentage share of net sales*
Molecular Diagnostics	50%
Academic	22%
Pharma	19%
Applied Testing	9%

Molecular Diagnostics
Physicians, hospitals and healthcare providers use QIAGEN technologies to save lives and fight disease. Our products support disease prevention such as screening women for risk of cervical cancer; profiling patients to pinpoint many diseases; personalized healthcare to guide treatment decisions; and point-of-care testing to provide on-site diagnosis.


Academic
Researchers at life science laboratories around the world depend on QIAGEN to advance our understanding of the molecular basis of life. Customers include universities and research institutes.

Applied Testing
Professionals in fields such as human identification and forensics, food testing and veterinary medicine use QIAGEN technologies in commercial applications beyond human healthcare. Our products are helping to solve crimes, secure food supplies and detect potentially devastating livestock diseases.


Pharma
Scientists in the pharmaceutical and biotechnology industries look to QIAGEN to advance gene-based drug discovery and development, supporting the creation of new medical breakthroughs.

*2015

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 GR System

GR System



The GR System provides a streamlined and standardized approach from sample preparation to the interpretation of sequencing data.

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 The «Main»-Team

QIAGEN Manchester - MDx Development Hub. NGS assay design competence. System and automation competence with a testing department for qPCR and NGS systems.

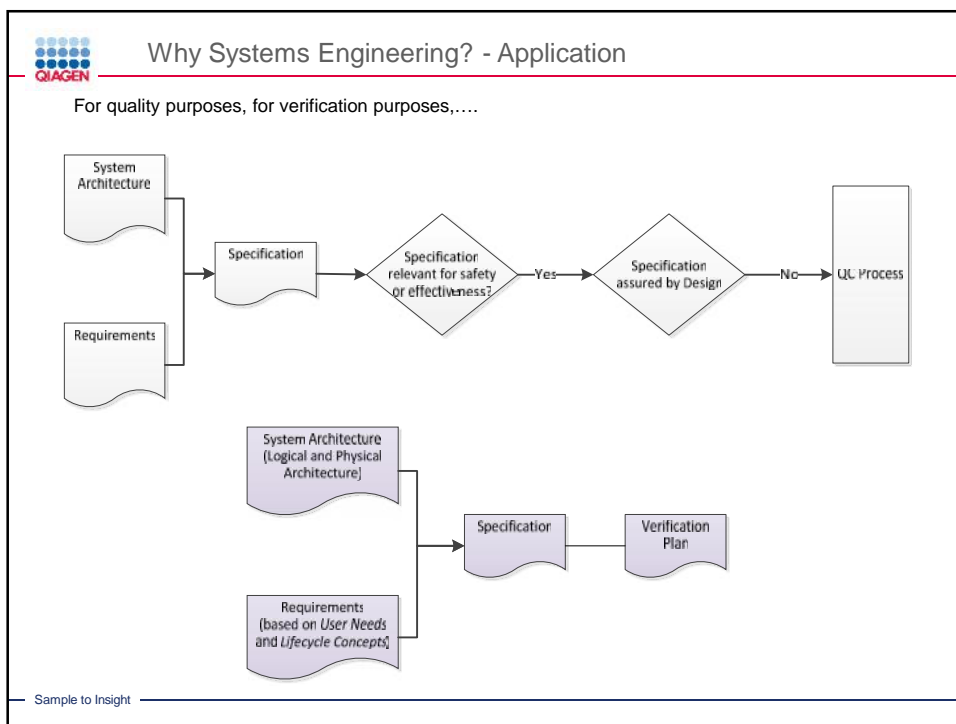
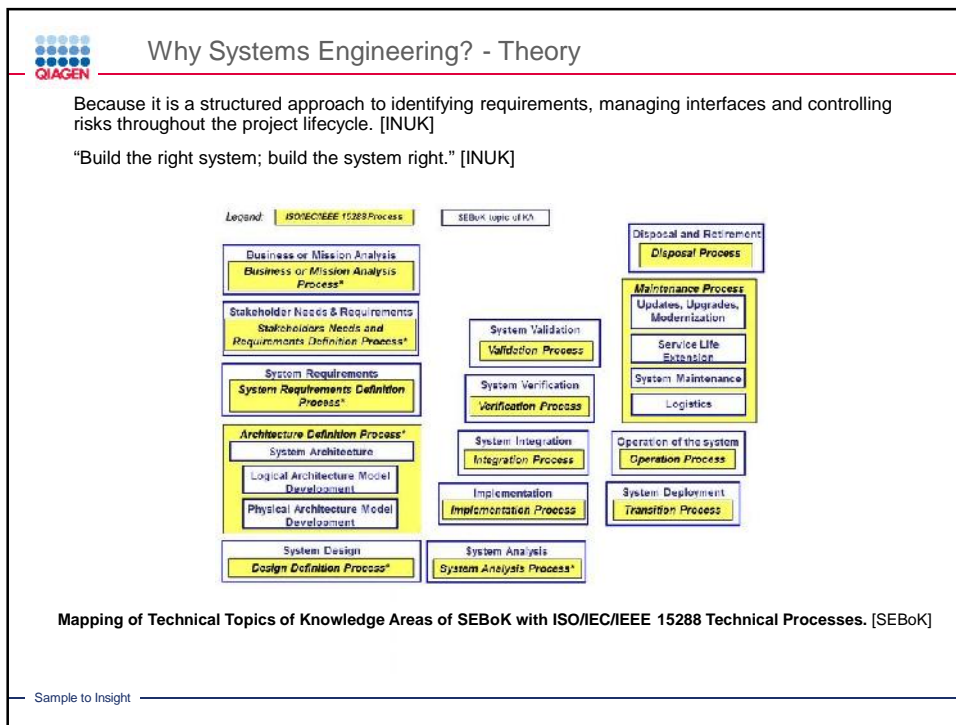
QIAGEN Waltham - NGS Platform Technology Innovation Center. Focus: Create the next generation of NGS platforms.


QIAGEN Hilden - Center for Preanalytics, Workflow Architecture, Software and Algorithm Development.

QIAGEN Hombrechtikon - Center for System Engineering and Development. Focus: "Digitizing biology."

QIAGEN Aarhus - Bioinformatics

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Why Systems Engineering? - Concretely

.....for Development

- To Master the complexity
- To detect «Small -> BIG mistakes»
- Shrinking product lifecycles
- Decisions and implications
- Because local «optimum» does not mean global «improvement» (trade-off studies)
- To «translate accurately» (“read” -> take pictures)
- To help the «customer» to express himself more «accurately» («small»)
- To «adapt» to «moving» requirements
- To assure that interfaces are well addressed
- To assure requirements/constraints are fulfilled

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Why Systems Engineering? - Concretely

.... For Quality

- Troubleshooting
- To ensure quality, by, for example, using subsystem integration and verification

System Testing

- To facilitate, plan, execute and report the system testing
- To **align the development process** by using progressive iterations.
- To enable the **progressive integration** of the “new” developments

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What is the Role of Systems Engineering in the GeneReader NGS System?

In my opinion, the System Engineer has two roles:

- a) «Enabling Role»: Due to the structured development approach, the Systems Engineer enables to build the right system AND build the system right.
- b) «Architectural role»:

LEGO-Blocks Analogy

The Development Team takes care of CONSTRUCTING the blocks.

The Systems Engineer takes care of the ASSEMBLY (Interfaces, Integration, Coordination).

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General Conclusion of this Presentation

Overall Message: Systems engineering enables a successful long term growth

How?

It gives a common framework for the «product development» (Language, Methods, Processes)

Challenge: The implementation. The framework needs «to be translated» to the company language/tools/metrics.

Example: A bioinformatician, a mechanical engineer and software engineer need to define the **System Architecture** of the system. Which software shall they use? How shall they represent the processes? And the simulations? UML/SysML, Matlab...


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**THANK YOU
QUESTIONS?
FOR YOUR
ATTENTION**

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Example of Role and Tasks

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Example of Role and Tasks

Instrument – Systems Engineer + Team

- Owner of documents/deliverables on instrument level
 - Owner of the System architecture documents (Instrument)
 - Owner of the Instrument specifications
 - Owner of the Interface specifications of modules
 - Coordination of tests /trials with the System Verification Team
 - Analysis methods (analytical methods, data analysis methods, error reporting)
 - Planning of trials
- In Scope
 - Transparency on system architecture and dependencies across all development teams
 - Constant review of the instrument for conflicting requirements
 - Ensure translation of Subsystems specifications to Instrument specifications is not conflicting
 - Second level troubleshooting on instrument level

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Example of Role and Tasks

Workflow – System Architect + Team

Owner of documents/deliverables on system level

- Owner of the System architecture documents and Workflow description
- Owner of the System level design specifications (turn-around time, reliability, usability...)
- Owner of the Interface specifications of subsystems
- Coordination of System Integration campaigns, System Verification (including execution of field tests)
- Analysis methods (analytical methods, data analysis methods, error reporting)
- Beta test site setup

In Scope

- System Integration campaign planning and execution
- Standardization of analysis methods across all development items
- Organisation of Implementation of Use
- Transparency on system architecture and dependencies across all development teams
- Constant review of system for conflicting requirements
- Ensure translation of Product Requirements to Subsystems specifications is not conflicting
- Second level troubleshooting on system level

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