The Role of Systems Engineering in the GeneReader NGS System

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

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
Why Systems Engineering? - Theory

Because it is a structured approach to identifying requirements, managing interfaces and controlling risks throughout the project lifecycle. [INUK]

“Build the right system; build the system right.” [INUK]

Why Systems Engineering? - Application

For quality purposes, for verification purposes,....
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

….. 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
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…
THANK YOU FOR YOUR ATTENTION

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Bibliography

[INUKE] https://incoseonline.org.uk/Documents/zGuides/Z1_What_is_SE.pdf
retrieved 21062016

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
## 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