Rational Systems and Software Engineering **Symposium**

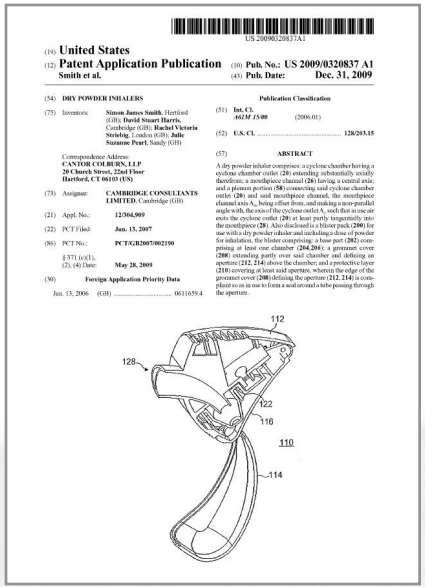
IBM

Systems Engineering – The Edge of Complexity?

For 50 years, Cambridge Consultants has led the way in innovative product development. We are the development partner of choice for many of the world's leading blue chips, as well as the virtual development team for ambitious start up companies.

Our work is mainly focussed on innovation, rather than evolutionary products.

- We have assigned over 3000 patents to our clients over our history.



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(54) **DRY POWDER INHALERS**

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(57) **ABSTRACT**

A dry powder inhaler comprises: a cyclone chamber having a cyclone chamber outlet (**20**) extending substantially axially therefrom; a mouthpiece channel (**24**) having a central axis; and a plenum portion (**58**) connecting said cyclone chamber outlet (**20**) and said mouthpiece channel, the mouthpiece channel axis A_m being offset from, and making a non-parallel angle with, the axis of the cyclone outlet A_c such that in use air exits the cyclone outlet (**20**) at least partly tangentially into the mouthpiece (**28**). Also disclosed is a blister pack, (**200**) for use with a dry powder inhaler and including a dose of powder for inhalation, the blister comprising: a base part (**202**) comprising at least one chamber (**204**,**206**); a generator cover (**208**) extending partly over said chamber and defining an aperture (**212**, **214**) above the chamber; and a protective layer (**210**) covering at least said aperture, wherein the edge of the generator cover (**208**) defining the aperture (**212**, **214**) is compliant so as in use to form a seal around a tube passing through the aperture.

We employ 350 scientists, engineers and technologists in the UK and a further 40 in the US.

- Typically, in a year, we undertake around 300 projects for our clients.
- We work in a number of fields, including defence, transport, wireless, and my own area of healthcare.
- So by the scale of many of the projects discussed here today some projects are small.
  - 15,000 man hours per year would be a large project for us, and many projects are much smaller.

At Cambridge Consultants we are enthusiastic systems engineers, and we have adopted systems engineering approaches for a number of projects:

- I am currently leading a project to identify and embed company wide systems engineering practices, tools and processes.
- We have recently made an investment in DOORS and Rational Quality Manager to support and simplify elements of our systems engineering approach.

But of interest to us, developers in a smaller project environment, at what point does formal systems engineering ease to be cost effective?

- When does architecting prove more trouble than it's worth?
- When do ICDs or interface specifications take longer to write than to just do the design?

For example, here is an inhaler to treat asthma, which we developed for Sun Pharmaceuticals Ltd, one of the largest pharmaceutical companies in India:

- It only has 16 components.
- Only around 100 top-level performance requirements.
- But despite the apparent simplicity, we adopted System Engineering principles in the development of this inhaler.
- Interfaces.

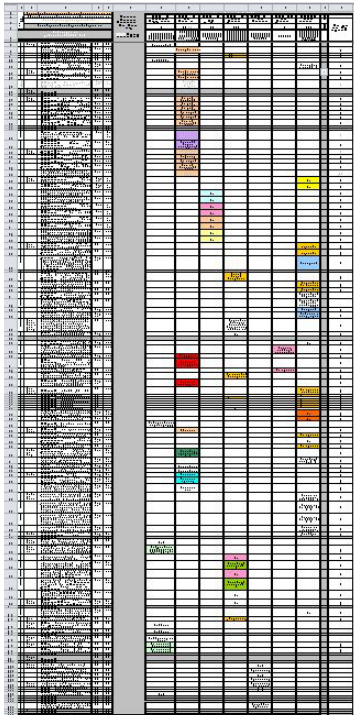
We had geographically dispersed interfaces.

- Drug development team in India.
- Device engineering team in Cambridge UK.
- Drug filling development team in Germany.
- Mould tool design (and manufacture) in Germany.
- Device manufactured and assembled in India.
- Drug manufacture, filling and final assembly in India.

In addition, we had a plethora of regulatory requirements.

Traceability was managed using an Excel spread sheet.

- Manageable, but inflexible and cumbersome.
- Even at this level, a requirements managements tool would have been helpful.
- Product lunched in 5 years.
  - Half the industry average.

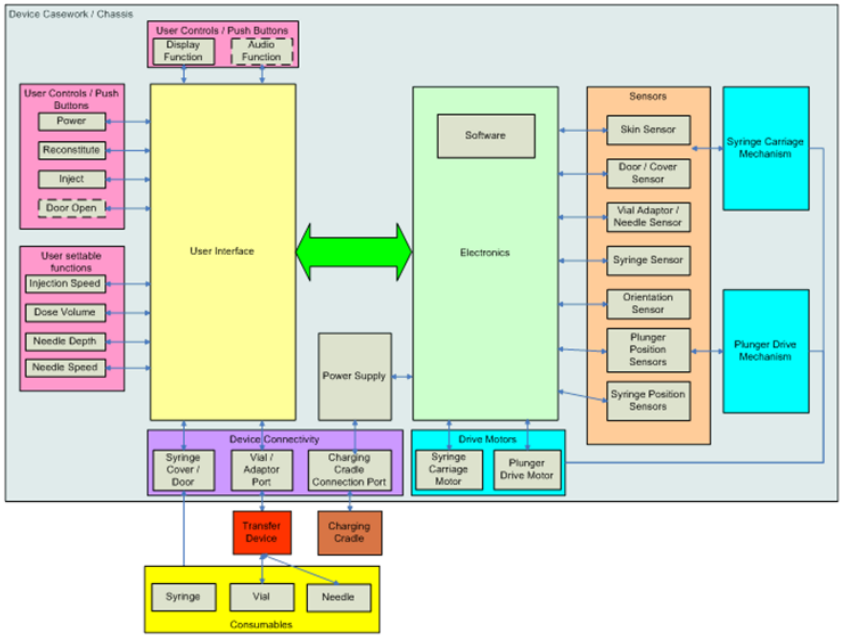


Another project was to develop a syringe driver for patients to self inject.

- This was a device that used electric motors for needle and fluid insertion, and software for control.
  - Not atypical.
- Around 120 top level performance requirements.
  - Excluding standards/regulatory.

The system breakdown was conventional.

- A system architecture definition document was written.
- Discipline-based specifications then followed.
  - Electronics Requirements Spec.
  - Mechanical Functional Spec.
  - Software Requirements Spec.



Writing next-level discipline based specifications, rather than module based specifications, was an attempt to reduce the amount of design documentation by not needing to define any inter-module interfaces.

- This was a misconception:
  - Interfaces needed to be specified in the Architecture document (nowhere else for them to go).
- 90 iterations of the architecture document.
- Use of Microsoft Word very inefficient.
- A requirements management tool may have helped us get out of this difficulty

Once again, traceability was managed in Excel.

- We had a similar number of top level requirements to the previous example.
- Has become difficult to manage, with multiple many to many relationships, mainly because of the multidisciplinary nature of the project.

46	**6.1.13(b)**	The device should indicate by visual and/or audible means that the device is close to the end of its use life (i.e. two years of use = 400 uses)	M	This is mostly missing though S.20 records the number of uses.	Needs the LED status to be described and added to initialisation state diagram			
47	**6.1.15**	Operators must be able to clearly distinguish between an unused, in-use, and a disabled device. The device shall provide visual feedback indicating clearly the state of the device (i.e. unused, ready for use or disabled). This will be verified through simulated use testing. (ISO 11608-4 section 5) & (ISO/DIS11608-5 section 4.1)	M	M.8				
48	**6.1.17**	A minimum of two manual action(s) must be required in order to use the system, i.e. from locked to unlocked state/ready for the injection. (ISO/DIS11608-5 section 4.3.2)	M	M.8				
49	**6.1.26**	In the case of a device failure or process interruption the patient should be able to reinitialise the device to allow it to be loaded with new disposables.	S	M.8	How is the device reinitialised?			
50	**6.2.1**	Must not allow more than 0.05 mL of reconstituted solution to leak from the syringe in normal use.	M	M.13 2), M.107, E.36				
51	**6.2.2**	Must indicate to the operator by visual, audible or tactile means that the device is ready for injection.	M	M.8				
52	**6.2.3**	Must have a state once the dose has been delivered that is different to the state when ready to deliver a dose. This difference must be readily identifiable by the operator.	M	M.8				
53	**6.2.4**	Must offer tactile, visual, or audible feedback within the final 10 % of the reconstitution cycle to confirm to the operator that reconstitution has been completed successfully. This feedback will be co-ordinated with the final step of the reconstitution cycle as defined in the cRAI Glossary, P0256-GLOS-001.	M	M.1, M.3, M.8, E.16, S.34 20) and S.34 21)	Timing of the beep isn't discussed in the electronics / software sections? Sequence of beeps/lights isn't adequately described in satte diagrams as yet in software			
54	**6.2.5**	Must offer tactile, visual, or audible feedback within the final 10 % of the injection cycle to confirm to the operator that the injection has been completed and the needle has been safely retracted inside the housing.	M	M.1, M.3, M.8, E.16, S.34 20) and S.34 21)	Timing of the beep isn't discussed in the electronics / software sections? Sequence of beeps/lights isn't adequately described in satte diagrams as yet in software			
55	**6.2.6**	Must not generate noise greater than 80dBA at a distance of 1.0m. (To allow the patient to receive a dose discreetly)	M	M.56, M.82	Noise data is complete			
56	**6.2.7**	Must indicate to the operator by visual, audible or tactile means that the device is ready for injection.	M	M.1, M.3, M.8, E.16, S.34 20) and S.34 21)	Sequence of beeps/lights isn't adequately described in satte diagrams as yet in software section.			
57	**6.2.8**	Must have a minimum battery life sufficient for 4 use-cycles between charging.	M	E.54	Not enough detail to trace			
58	**6.2.9**	The Charging cradle and the Device must be suitable for mains charging at 100-250VAC, 50-60Hz (External medical approved charging block may be used.)	M	Section 3.9, section 4.7, 5.8	Need more detail on all of these.			
59	**6.2.12**	Must not be possible to use the device if the battery has not enough energy to complete the use-cycle as defined in as defined in the cRAI Glossary, P0256-GLOS-001.	M	S.4, S.34, S.14 and appendix 1				
60	**6.3.1**	The device excluding consumables must fit within 70 mm x 100 mm x 185 mm space envelope.	M	O.45				
61	**6.3.2**	The device excluding consumables must have an unpackaged weight of no more than 420 g.	M	O.46				
62	**6.3.3**	The device excluding consumables should fit within 60 mm x 85 mm x 160 mm space envelope.	S	O.45	60x74x163mm			
63	**6.3.4**	The device excluding consumables should have an unpackaged weight of no more than 350 g.	S	O.46	381g			
64	**6.3.5**	The Device and Transfer Device must have a clear method of interfacing together	M	Section 3.3.2 M20-21				
	6.3.6	The Operator should not be able to interface the Transfer	S	M.9	Table is incomplete			

We were approached by a US diagnostics company to help with the stalled development of a diagnostics instrument.

- Chemistry in California.
- Manufacturing in France.
- Software in Israel.
- 800 lines of requirements.

And no progress!

We took on the role of systems integrator and partitioned the system

- Took the 800 lines of requirements and allocated them the User Requirements, Product Requirements, System Architecture and Implementation Specifications as appropriate.
- Took 3 months of work in Excel.
- Once again, the driver was our fear of traceability.

For this project and product we adopted a full architecture approach, with module, sub-module and discipline level specifications.

- System engineering team.
- ICDs.
- Detailed modelling of interface.
- Simulator for software interfaces.
- System models for budget allocations.
- System integration team.
- Traceability was a real issue.
  - Modelling in UML, and controlled in EA.
  - Generated a requirements traceability model.
    - Took a considerable amount of effort.

We have recently adopted DOORS and RQM, and are in the process of rolling it out across the company.

- In use on a trial project that has multiple components.
- First impressions are that it simplifies many of the requirement capture processes.

ID	Clause	Comment	Source	Priority	Proof of Feasibility Concept A (D	Proof of Feasibility Concept B
P1702-RS-003-1552	**4.1.1 Volumetric Performance**			Not Applicable	Not Applicable	Not Applicable
P1702-RS-003-1137	There must be a 95% confidence that 97.5% of all doses delivered (volume) are within +-10% of the selected dose volume (TBC)	From ISO 11608-1	Extrapolation of previous requirements specification	Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling
P1702-RS-003-1138	There must be a 95% confidence that 97.5% of all doses delivered (activity) are within +-TBC % of the nominal dose activity (TBC)	From ISO 11608-1	Extrapolation of previous requirements specification	Medium	Analogy or No Feasibility - Low Risk Requirement	Analogy or No Feasibility - Low Risk Requirement
P1702-RS-003-1143	The target fill volume of the 2ml Container must allow for priming and delivering a target dose of 2ml	No priming may be a requirement	Extrapolation of previous requirements specification	Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling
P1702-RS-003-1547	The target fill volume of the 10ml Container must allow for priming and delivering a target dose of 10ml	No priming may be a requirement	Extrapolation of previous requirements specification	Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling
P1702-RS-003-1146	Must require less than TBD % overfill.			Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling
P1702-RS-003-1178	Container must allow no more that xxml residual drug after full delivery TBD			Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling
P1702-RS-003-1147	Must allow no more than TBD air bubble inside sealed device at atmospheric pressure			Medium	Practical Demostration via Functional Rig/Prototype	Practical Demostration via Functional Rig/Prototype
P1702-RS-003-1548	Should have no air bubble inside sealed Container at atmospheric pressure			Medium	Practical Demostration via Functional Rig/Prototype	Practical Demostration via Functional Rig/Prototype
P1702-RS-003-1162	2ml Container must operate normally with a minimum fill volume of 0.3ml			Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling
P1702-RS-003-1196	The 2ml container must be capable of delivering a single dose from 0.3ml to 2ml in volume			Medium	Analysis, Simulation or Modelling	Analysis, Simulation or Modelling

Cambridge Consultants has concluded that systems engineering is an appropriate approach for a product development of even moderate size or complexity.

- Architecture and subsequent level of documentation should be driven by the optimum engineering approach, not by attempts to minimise documents.
- Effective collaboration is only possible through a systems engineering approach.
- A requirements management tool will not only make the project more efficient when used on optimum architectures, it will probably also allow the better development of sub-optimal architecting.

Thank You.