SPARKL_®

Case Study Factory of the Future Quality Assurance in Manufacturing

Proof-of-Concept SPARKL[®] Cisco GSK Pharmaceutical companies spend billion of dollars developing, marketing and distributing drugs to the public. It is a complex, intricate process.

But for decades, many factories have been manufacturing drugs in rather dated <u>ways</u>. According to Wall Street Journal, the process of making pills consists of "mixing ingredients in large vats and in separate steps, often at separate plants and with no way to check for quality until after each step was finished."

The USA alone <u>consumes</u> 16,000 tonnes of aspirin tablets a year - that's 80 million pills for a manufacturer to produce and distribute.

Yet a lack of transparency and efficiency in the supply chain is still preventing drug-makers from being able to fully innovate the manufacturing process in factories around the world.

Any moves to modernise the process have been blocked by cost, complexity and regulation. Ageing factory equipment gaining wear-and-tear are used time and time again, resulting in a severe knock-on effect for pharmaceutical companies around the world.

The industry's supply chain is an increasingly fractured one, and could fall apart instantly in the event of unplanned downtime. This can <u>cost</u> factories as much as \$2 million for a single incident.

Preventing these incidents from happening again is difficult when there are regulatory constraints preventing process improvements from being made. The manufacturing process of any new drug has to be approved by a regulatory agency, and thus many companies have continued to use the same processes for decades.

Making changes to the manufacturing process post-launch is expensive, yet also runs the risk of things getting worse. These methods are set in place well before the start of clinical trials, meaning that it is almost impossible to make any changes throughout drug production.

SPARKL and **Cisco** worked with pharmaceutical giant **GSK** to develop a proof-of-concept (PoC) using the SPARKL technology in an effort to solve these challenges.

SPARKL is powerful technology for managing the behaviour of distributed machines, systems and applications. The lightning fast SPARKL Sequencing Engine uses our simple, declarative Clear Box[®] configuration to make these things work together intelligently - generating a blockchain-secured audit trail.

SPARKL lets you design and execute business processes - or mixes - to manage things such as smart contracts, technical infrastructure and industrial factory machines.

Established by GSK and SPARKL, the goals of the proof-of-concept were to:

- Create digital profiles (unique identity and structured relationship definitions within the train) for physical devices, e.g. motors and screw feeds. This creates smarter, more intelligent assets
- Monitor and analyse the pill production train, identifying operational anomalies and gaining a more accurate and relevant picture of asset status
- Gain simple access to live and historical asset visualisation, providing consolidated activity related to equipment, lines and products during manufacturing
- Open web objects representing physical assets, enabling other business applications to tap into the new wealth of asset information

As a result, SPARKL created a digital profile system for physical devices in a specific pill production train for GSK.

This system enabled the devices to spot anomalies within its pill production train in operation, therefore:

- Eliminating tasks from the scheduled maintenance procedures, focusing only on work that is necessary to maintain compliance and performance
- Predicting failures in advance, reducing negative impact on production
- Extending the operational lifetime of production equipment and components, whilst maximising performance opportunity
- Understanding why a machine or component has failed
- Taking advantage of a component upgrade potential to maximise operational performance over longer periods

The PoC is based on SPARKL's finite-state machine (**FSM**) approach, featuring a breakout detection algorithm:

"A finite-state machine is a [computing] model used to represent and control execution flow. It's perfect for implementing artificial intelligence... Producing great results without complex code."

With this approach, SPARKL can detect anomalous trends in log data generated by predetermined workflows, called breakouts. Possible breakouts are confirmed as such by an admin, so that the algorithm learns without requiring pre-training. SPARKL operates on a "plug-and-play" principle—i.e. almost no programming or manual intervention required. The technology was installed onto Intel Arduino and Edison boards. Small but powerful, they deemed suitable for the PoC as they easily connect to wireless networks, and additionally work over Linux and Ubuntu for which SPARKL has been primarily developed.

SPARKL lets you configure the behaviour of every system – from applications right down to network infrastructure – to make them work together.

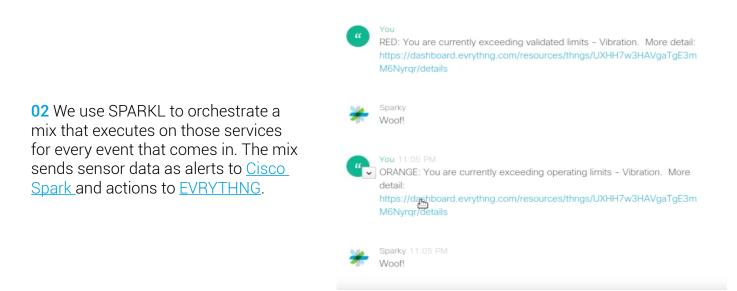
In this PoC, SPARKL was configured to pick up sensors attached to a non-vibrating part of a particular factory machine.

Readings were taken for vibration, speed and temperature. Depending on the status of the readings, SPARKL would be in a red, orange or green state. If a sensor exceeded its operating range, this was indicative of a problem requiring investigation.

This could be applied in a number of scenarios. For example, a disproportionate temperature in the manufacturing of a particular vaccine could render the batch unusable.

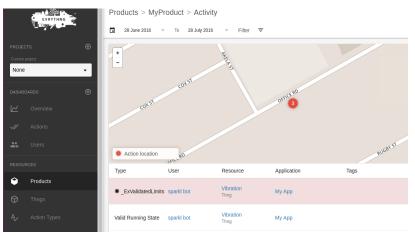
01 Two sets of mixes are written in Python on the SPARKL Developer Console, which is a dashboard where our users can build, execute and test mixes. It can be seen below in the screenshot. One mix pulls data into SPARKL from a REST interface, and another which acts on, and processes this data.

SPARKL [®]	% http://192.168.56.101:8000/	Home > Scratch > PharmaAccelSensors		1 Import file				
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	= thngid	10 import os						
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	= DONE_LOCAL	10 Uning id – "UNHH /WSHAVgaigesminonyrdr" 17						
	= DONE_MONGO	<pre>18 def main((collect, _register), fields):</pre>						
	III EventSource	19 while True: 20 # Pull dummy data from file						
	III EventProc	21 # x						
	≭ MyLogger	<pre>22 xindir = [x for x in os.listdir("/tmp")</pre>						
	PharmaTurretFSM	<pre>23 if x.startswith("pharma_accelerometer.x.")] 24 xindir.sort()</pre>						
		25 xdata = 0.001						
		26 if len(xindir) > 0:						



03 If a sensor is in a red or orange state, it is anomalous. An admin is notified over Cisco Spark and EVRYTHNG with an alert. SPARKL stores this data over a local cache service, so it can be locally analysed.

The screenshot below shows the speed of the pill train has dropped significantly, putting the FSM in a red state. An admin is alerted in Cisco Spark and EVRYTHNG (displayed as a red action).



04 The event logs from this mix are forwarded through a database on <u>MongoDB</u>— and the data is studied and visualised using <u>SlamData</u>.

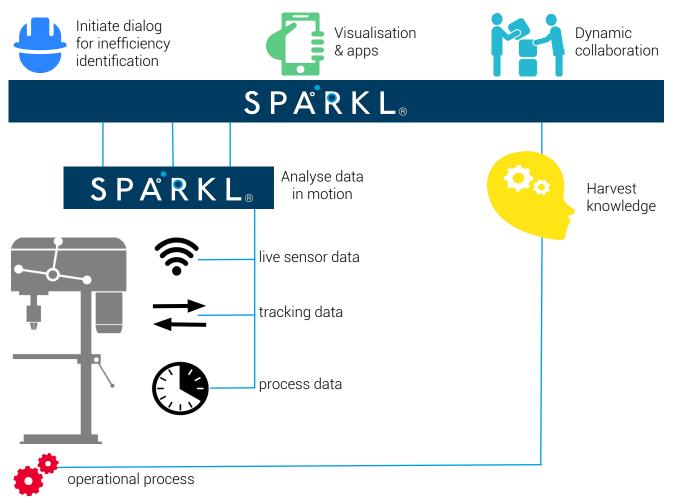
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Factory of the Future

The admin provides feedback on whether the state designation, determined automatically - with no pre-training required - was accurate or not. The breakout detection algorithm then trains itself to recognise specific types of pill trains.

The SPARKL and GSK proof-of-concept achieved all of the objectives highlighted earlier in the document, and was therefore deemed successful.

By the simple act of introducing sensors into the manufacturing process, key performance attributes can be corroborated together with the easy deployment of SPARKL with FSM + breakout detection, and immediate benefit can be obtained out-of-the-box. SPARKL can easily detect anomalies in sensor data readings, and alert admins to take action, if needed.



creating intelligent info sources --- creating insight --- enabling decision to act

This demonstrates how new insight can be created from sensing, monitoring and analysing data from a pill production train. This substantially reduces the risk of product quality failures, as GSK would be able to make any corrections throughout production, and not just after a batch is finished.



- Want to see more? Drop the team an e-mail at talk@sparkl.com
- See SPARKL tutorials and demos at sparkl.com/docs