



## Case Study

# Quality Assurance in Manufacturing

## Proof-of-Concept

SPARKL

GSK

SPARKL® Limited 2016

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# About SPARKL

## Bring Machines Together

All enterprises suffer from the black box swamp. Systems that work fine on their own, but won't play nicely with others.

It's hard to describe how a system should work - let alone how or why different systems interact.

SPARKL® is powerful technology for managing the behaviour of distributed systems. The lightning fast, distributed SPARKL Sequencing Engine drives events between machines, applications and things.

It provides Distributed Intelligence for true fog computing, allowing edge devices to interact with or without the cloud.

It introduces Reasoned Provisioning which spins up secure, on-demand infrastructure to meet the need of actual business logic.

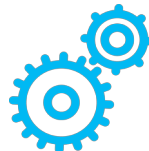
Secured by blockchain, SPARKL logs every single event in a clean, connected Audit Trail to solve compliance and regulatory reporting across machines and systems, old and new.

SPARKL designs and develops the SPARKL® Sequencing Engine in London, UK. We work with partners including Cisco and Intel to market the product to innovators and customers worldwide.



### **Finance**

Managing data  
provenance and  
security breaches



### **Manufacturing**

Automating and  
monitoring machine  
processes



### **Internet of Things**

Choreographing  
devices in smart  
cities and robotics

# The Manufacturing Challenge

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 in rather dated [ways](#), *"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 [consumes](#) 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 drugmakers 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, which can [cost](#) 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.

In early 2016, **SPARKL** and **Cisco** worked with British pharmaceutical giant **GSK** to develop a proof-of-concept (PoC) using the SPARKL Sequencing Engine technology, in an effort to solve these challenges.

# About the Proof-of-Concept

The goals of the PoC were established by SPARKL and GSK:

- **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

For the PoC, SPARKL created a digital profile system for physical devices in a specific pill production train, e.g. motors and screw feeds, creating smarter, more intelligent assets.

This 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](#)) technology, 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 in games, producing great results without complex code."*

It's also very useful for SPARKL's purposes. The Sequencing Engine is able to detect anomalous trends in log data, called breakouts. Possible breakouts may be confirmed as such by an admin, so that the algorithm learns without requiring pre-training.

# How it Works

SPARKL operates on the “plug-and-play” principle – i.e. almost no configuration or manual intervention required. So, the FSM was installed onto Intel Arduino and Edison boards. Small yet powerful, these boards were 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.

With the SPARKL Sequencing Engine, you can 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 factory machine.

Readings were taken from a wealth of different sensors across the factory floor, such as vibration, speed and temperature. Depending on the status of the readings, the Finite State Machine would be in a 'Red', 'Orange' or 'Green' state.

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.

1. Two sets of mixes (SPARKL config handling interactions between machines) are written (in Python) in the SPARKL Developer Console – one which pulls data into SPARKL, and one which acts on, and processes this data.

The screenshot displays the SPARKL Developer Console interface. On the left, a sidebar shows a project tree with the following structure:

- SPARKL
  - Home
  - Sequencer
  - Connection
  - Scratch
    - Logger
    - Event
    - Log
    - PharmaAccelSensors
      - PullScript
      - Transformer
      - LocalStore
      - EvrythngEvent
      - MongoStore
      - = \_\_primaryKey
      - = \_\_timestamp
      - = \_\_source
      - = \_\_field
      - = value
      - = thngid
      - = Log
      - = START
      - = DONE\_ET
      - = DONE\_LOCAL
      - = DONE\_MONGO
      - EventSource
      - EventProc
      - MyLogger
    - PharmaTurretFSM

The main area shows the configuration for the 'PharmaAccelSensors' project. It includes an 'Access Rights' table and a 'Source' code editor.

Pattern	Permission
*@test.com	read execute
*@sparkl.com	read execute
*@pharma.com	read execute

```
<?xml version="1.0"?>
<folder name="PharmaAccelSensors">
  <grant to="*@test.com" permission="rx"/>
  <grant to="*@sparkl.com" permission="rx"/>
  <grant to="*@pharma.com" permission="rx"/>
  <service name="PullScript" provision="script">
    <prop name="script.op.PullAcceLData" type="python">
      # use python2
      #
      import os
      import logging
      from time import sleep

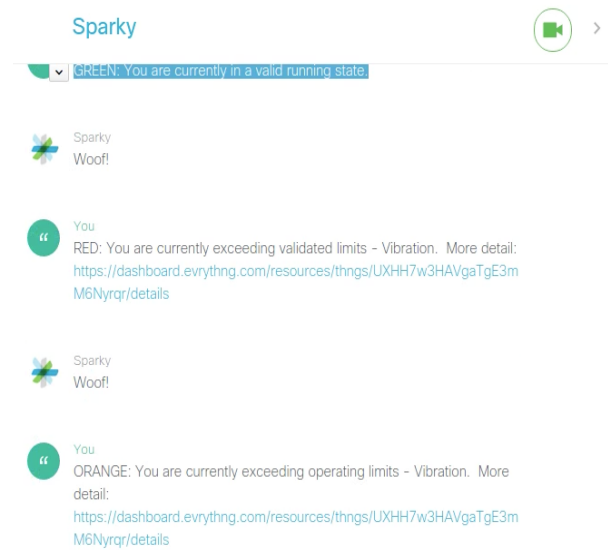
      logger = logging.getLogger(__name__)

      thngid = "UXHH7w3HAVgaTgE3mM6Nyrqr"

      def main((collect, _register), fields):
          while True:
              # Pull dummy data from file
              # x
              xindir = [x for x in os.listdir("/tmp")
                        if x.startswith("pharma_accelerometer.x.")]
              xindir.sort()
              xdata = 0.001
              if len(xindir) > 0:
```

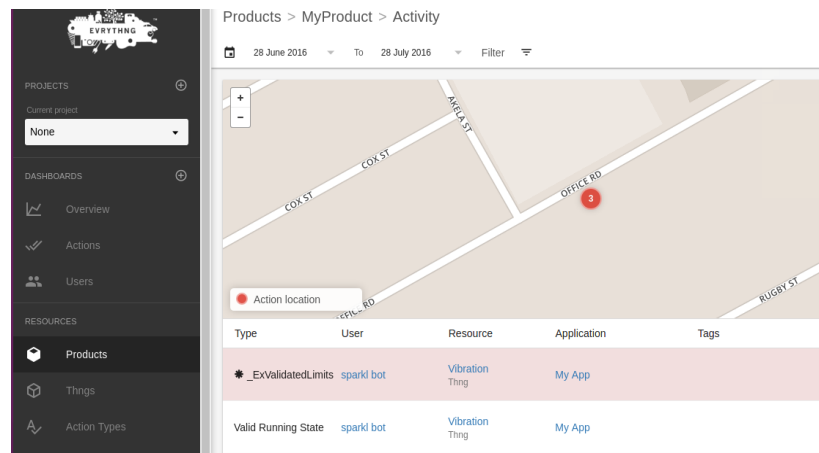
# How it Works

2. SPARKL orchestrates a workflow to execute on those services for every event that comes in. The mix sends sensor data as alerts to Cisco Spark and actions to EVERYTHING.



3. If a sensor is in a 'Red' or 'Orange' state, and therefore anomalous, an admin is notified over Cisco Spark and EVERYTHING with an alert. SPARKL stores this data over a local cache service, so it can be locally analysed.

Example: Here, the accelerometer has dropped significantly, putting the FSM in a 'Red' state. An admin is alerted in Cisco Spark and EVERYTHING (displayed as a 'Red' action).



4. The event logs from this mix are forwarded through MongoDB — and the data is studied and visualised using SlamData Analytics.

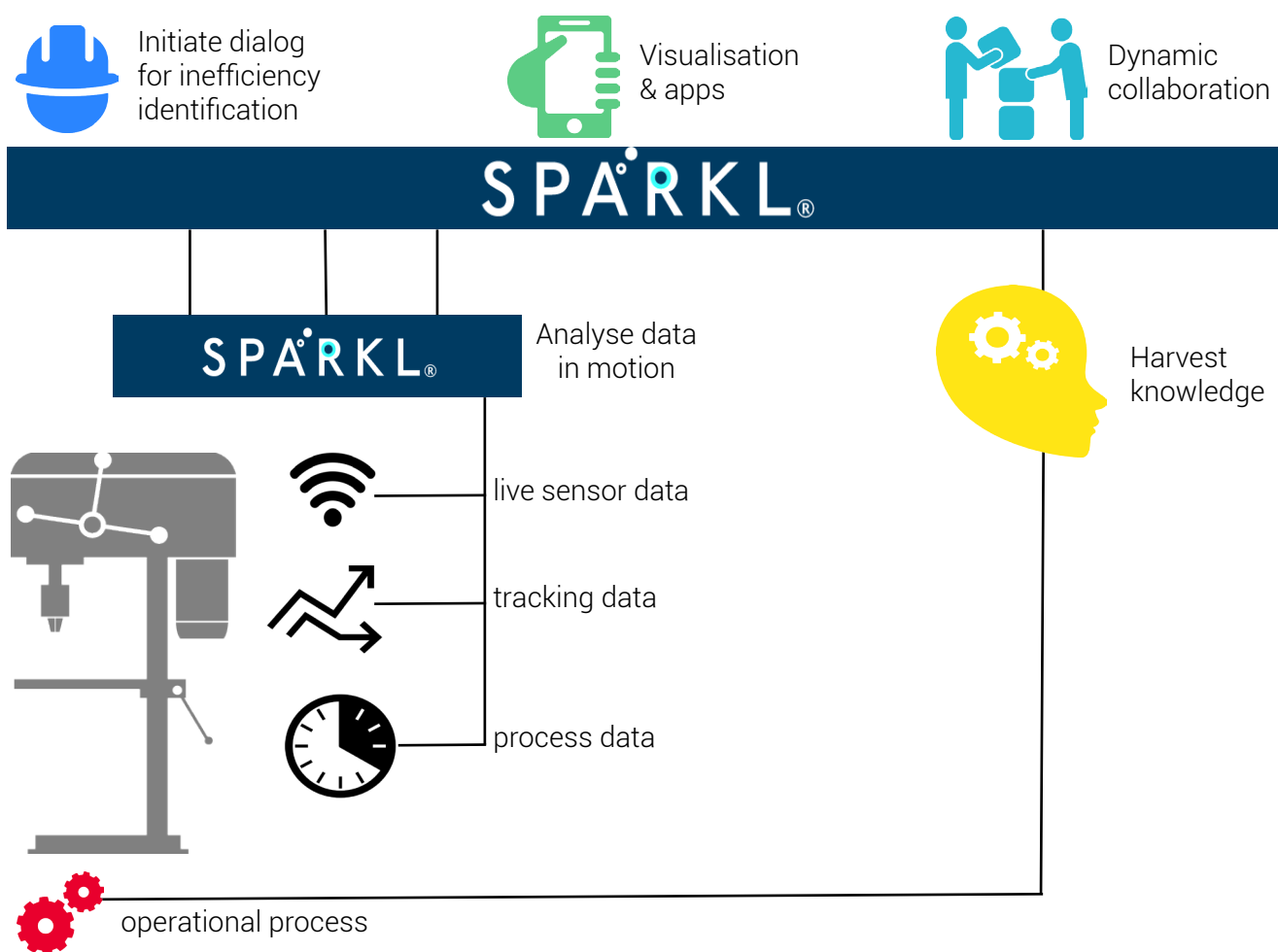
_field	_source	_timestamp	thngid	time	value
accelerometer_x	D-W2L-1BFE-C2	1455278793566	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:35Z	0.001
accelerometer_y	D-W2L-1BFE-C2	1455278793567	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:35Z	0.001
accelerometer_x	D-W2L-1BFE-C2	1455278796566	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:36Z	0.001
accelerometer_y	D-W2L-1BFE-C2	1455278796573	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:36Z	0.001
accelerometer_x	D-W2L-1BFE-C2	1455278799576	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:39Z	0.001
accelerometer_y	D-W2L-1BFE-C2	1455278799576	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:39Z	0.001
accelerometer_x	D-W2L-1BFE-C2	1455278802580	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:42Z	0.001
accelerometer_y	D-W2L-1BFE-C2	1455278802583	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:42Z	0.001
accelerometer_x	D-W2L-1BFE-C2	1455278805587	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:45Z	0.001
accelerometer_y	D-W2L-1BFE-C2	1455278805590	UXHH7w3HAVgaTgE3mM6Nyrqr	2016-02-12T12:06:45Z	0.001

# Quality Assurance

The administrator would also provide feedback on whether the state designation, determined automatically - with no pre-training required - was accurate or not. The breakout detection algorithm would then train 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, immediate benefit can be obtained out-of-the-box. SPARKL can easily detect anomalies in sensor data readings, and alert admins to take action.



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

This figure 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.

# Find Your Use Case

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