Electronic record keeping in the era of FSMA
Moving beyond paper and Excel

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Moving beyond paper logs and excel
The Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011. It is the most sweeping reform of the United States’ food safety laws in over 70 years. The overall objective of FSMA is to focus on prevention of food safety issues.

One of primary components is “Records Review” which has mandatory records and specifics for verification, accuracy, timeliness, retrievability and change proof-ness.

www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm
Mobile systems for data entry

- Relatively low cost + feature rich phones and tablets
- Relatively low cost + feature rich software
- Capture the data where and when it occurs
- Water and dust proof: IP67 and IP68
FDA required computerized records must:

- Be authentic, accurate and protected
- Provide accurate and complete copies of records
- Protect records for later retrieval
- Limit access to authorized individuals
- Provide a secure record audit trail
- Be reviewed by a trained individual

www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm
Pros and cons of paper

Benefits
✓ Known process
✓ No cost at start of process

Challenges
✓ Easy to falsify (“pencil whipping”)
✓ Doesn’t enforce rules
✓ Doesn’t notify in case of non-compliance
✓ No real-time visibility
✓ Can’t get meaningful statistics without post-processing
Why do we care?

- Identify issues sooner, resulting in better product / fewer issues / etc.
- Huge time/cost savings
  - 45% increase in plant throughput
- Big reduction in employee effort
  - > 20% increase in QA staff efficiency
  - Managers save 4+ hours per day
- Looks great when customers come to visit (competitive advantage)
Desirable Features

- Simplicity
- Pictures
- Barcodes
- Location aware (indoors and outdoors)
- Feature rich reporting
- Able to integrate with existing systems
- Passive presence verification
- Electronic supervisor sign-off
- Change logging
- User configurable inputs
- Works offline
- Multi-language support
Feature: user configurability and simplicity

- If it isn’t easy to use (admin + workers), it won’t get used
- Admins able to change what data is collected “on the fly”
  - Should also be able to modify reports quickly
- Lowers cost
- Lowers implementation time
- Lowers resistance to adoption
Feature: secure cloud based architecture
Feature: capturing pictures

- Problem: associating pictures to transactions
- Integrate pictures into your workflow
- Store in cloud with a public link
- Export links, integrate pictures into reports
Feature: scanning barcodes

- Stock Keeping Unit (SKU)
  - Look-up the description, shelf life, min/max specifications per product
- Traceability through plant
  - Print as part of existing documents
  - Work order, bill of lading, seal
  - Sequentially numbered stickers
- 2D barcodes
Feature: being location aware - outdoors

- Capture location at time of entry
- Turn by turn navigation to known locations
- Geo-fencing
- Path trace
- Lo-Jack
Feature: being location aware - indoors

- “Passive presence verification”
- Barcode / QR code
- NFC (Near field communication)
- Bluetooth Low Energy (BLE) beacons
  - Low cost, low precision
- Emerging technologies
  - UWB. High cost, high precision (30cm)
  - LED. Unknown cost, high battery usage
  - Google Visual Positioning Service
Feature: reporting

- Types of reports
  - Issues and exceptions
  - Trending over time (graphs and charts)
- Email or text staff in response to events
- Scheduled emailing of PDFs
- 3rd parties too!
  - Restricted, view-only logins
  - Emailed summaries/COAs
Feature: able to integrate

- **ERPs**
  - Product lists, bill of material
- **Laboratories**
  - Results and COAs directly from labs
- **Plant hardware (PLCs)**
  - Charts, trends, exception based reporting
Example use cases

- Hourly/daily/weekly checks
- Field inspection with lab samples
- Harvest inspection with sales dashboard
- Raw product evaluation
- Truck tracking
- Finished product evaluation
- Maintenance/sanitation
Why we care, revisited

- Compliance to regulations
- Identify issues sooner, resulting in better product / fewer issues / etc
- Huge time/cost savings
  - 45% increase in plant throughput
- Big reduction in employee effort
  - > 20% increase in QA staff efficiency
  - Managers save 4+ hours per day
- Looks great when customers come to visit
Final thoughts

Rather than seeing the additional reporting requirements driven by both new FDA regulations and customers as a burden, see it as an opportunity. Companies that do a better job of data collection and reporting will be able to leverage that into increased efficiency, throughput, and quality. The right tools, implemented correctly, will not just ensure regulatory compliance, but will also be a competitive advantage in the marketplace.
One affordable solution for fast, easy and scalable mobile data collection and analysis across your entire organization