Statistics and SPSS: The Lifeblood of Product Quality

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Overview

- Overview of LifeScan Scotland and diabetes
- Use of SPSS at LifeScan Scotland
- "Making a difference" using SPSS
  - Product Quality
  - Product Improvements
- Round-up / Questions

Company Background

- LifeScan (a Johnson & Johnson company) manufacture blood glucose monitoring systems for people with diabetes

  - Systems are used to monitor blood glucose levels and results can be used to manage blood glucose levels (i.e. amount of insulin to inject)

  - Quality is vital and at the centre of everything we do

Products

OneTouch® Ultra Blood Glucose Monitoring System (BGMS)

Laboratory (Glucose) Analyser

Company History

- Inverness Medical Limited (IML) founded in Inverness in 1995, to develop and manufacture blood glucose monitoring systems (SMBG) for diabetics.

- Early products included Pocketscan, FastTake ED and Euroflash. Test time up to 30 seconds.

- In 2001, OneTouch® Ultra system launched – shorter test time (5 seconds), smaller blood volume

- Acquired by Johnson & Johnson in 2001 and subsequently renamed "LifeScan (Scotland)"

- Continuous pipeline of new products such as Induo, UltraLink, Verio, all with new innovations.

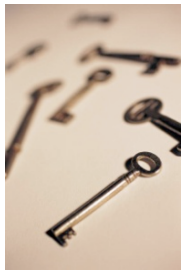
Johnson & Johnson

- Johnson & Johnson (J&J) one of the biggest healthcare companies in the world.
  - 250 operating companies
  - 57 countries
  - 114,000 employees

Diabetes

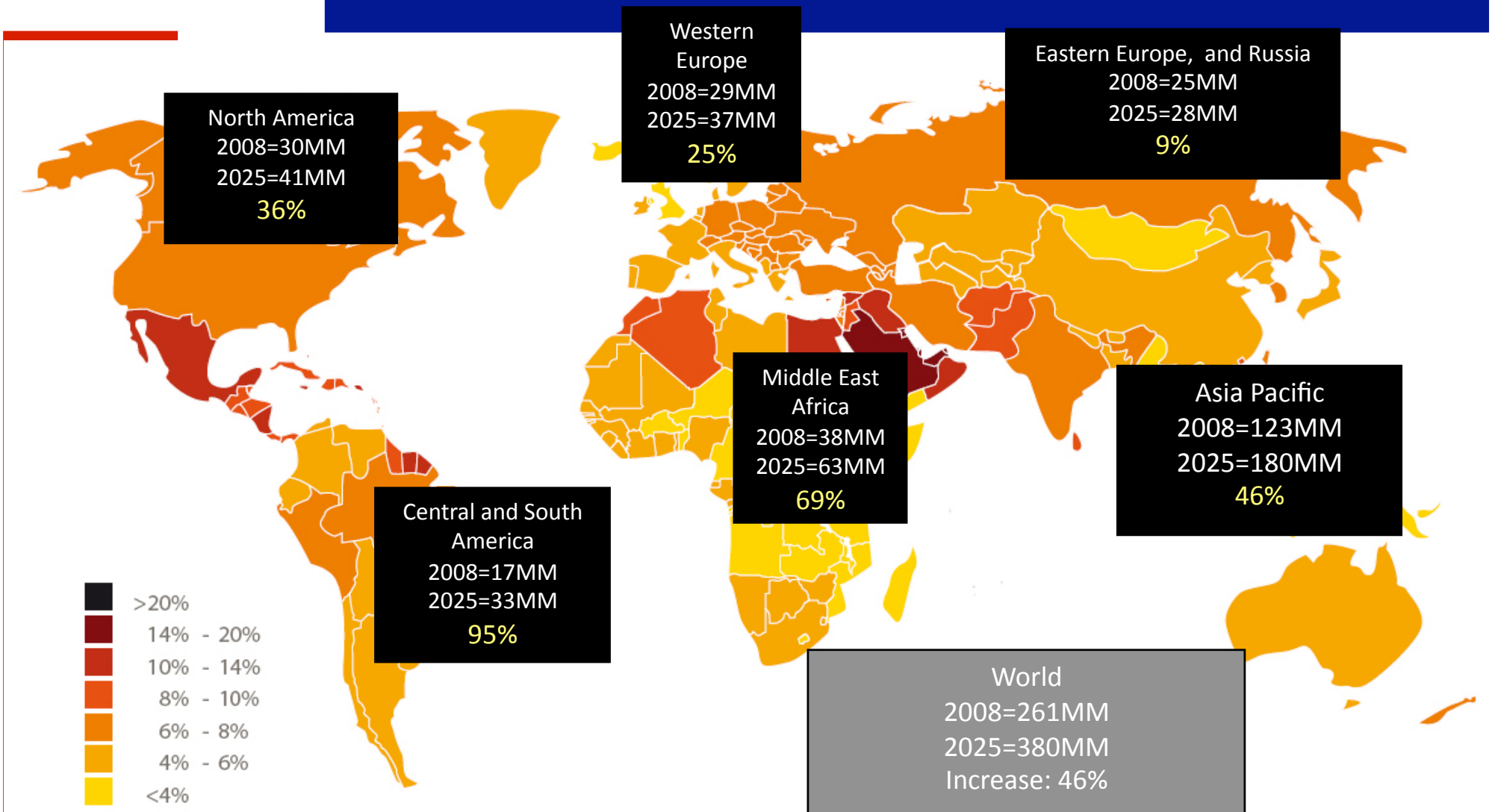
Glucose Metabolism

glucose



insulin

Prevalence of Diabetes

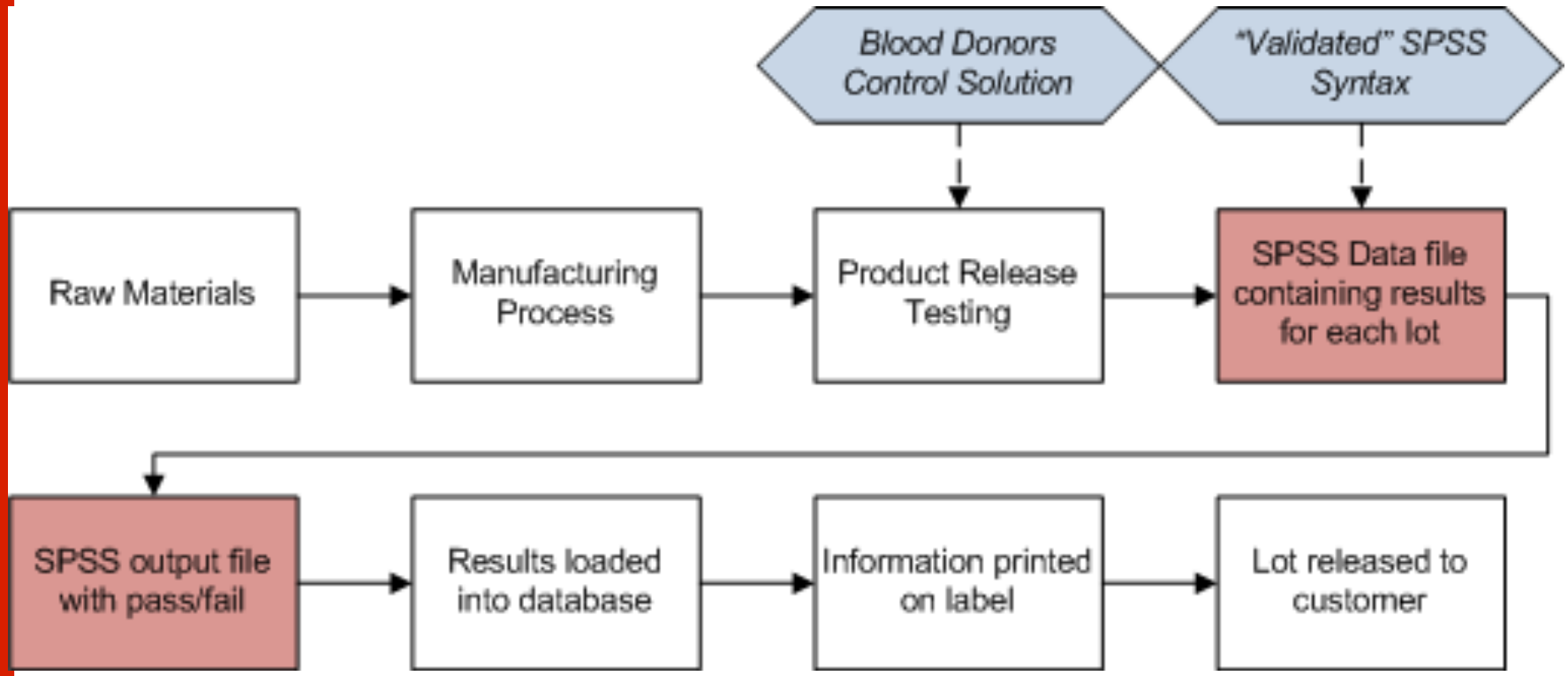


Zimmet P et al. *Nature.* 2001;414:782.

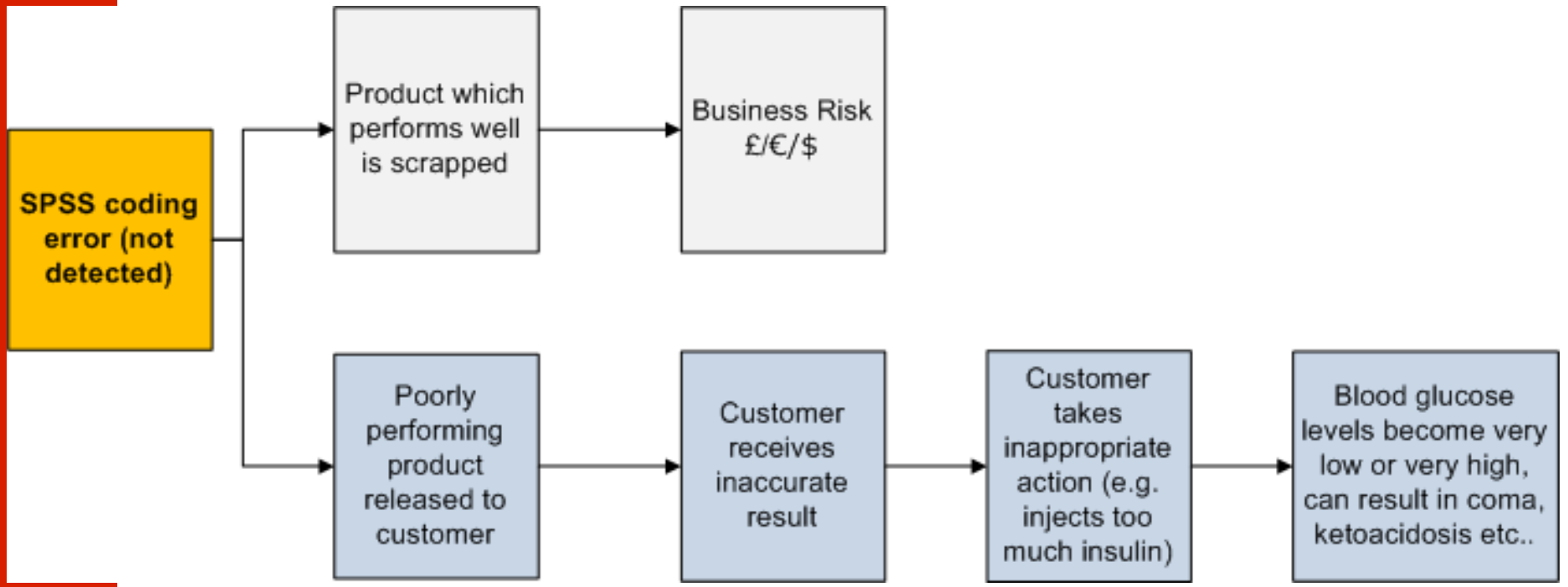
Use of SPSS at LifeScan

- SPSS is a business critical application at LifeScan
  - Used primarily to analyse results of laboratory & clinic testing data
  - Every lot of strips (~ 5,000 lots per year) is release tested and results analysed using SPSS to assess performance (pass/fail) and assign critical labelling information
  - Same programmes are used across multiple manufacturing sites (Inverness, Scotland and Aguadilla, Puerto Rico) to control release of product

Overview of Process



Why Product Quality is important



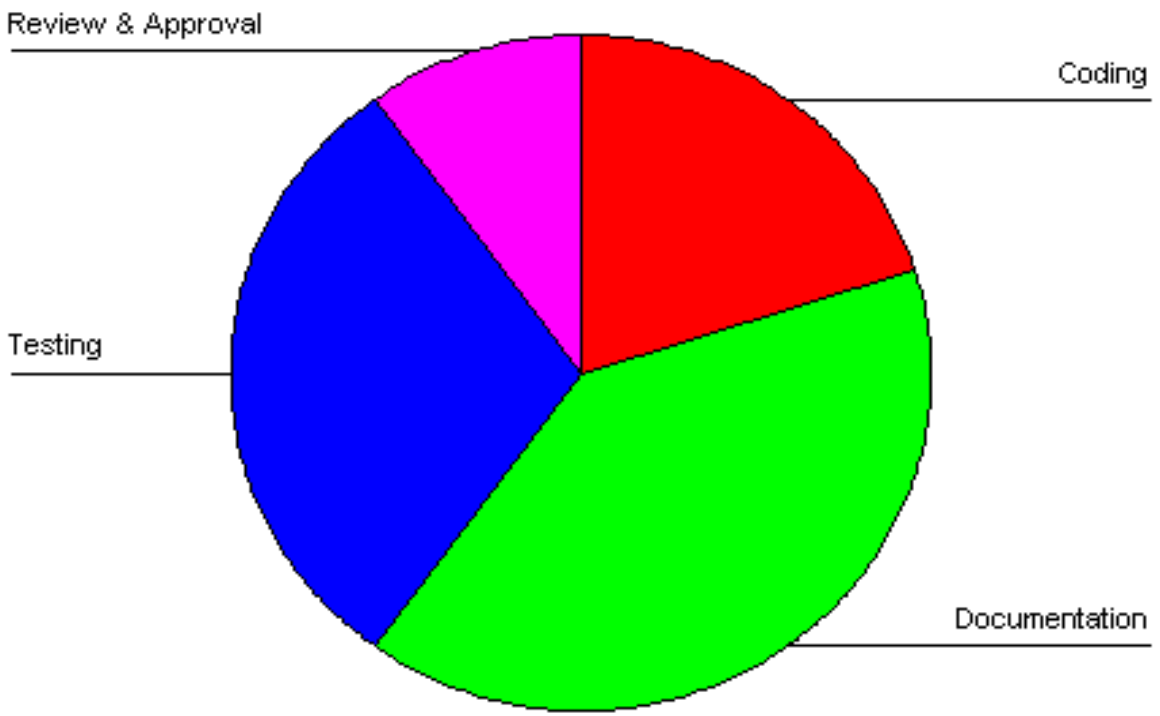
Emphasis on Product Quality

- As a result there is a large emphasis on getting things right before releasing any software into production

- Validation and Verification critical to ensure product safety and compliance to regulations and standards

Breakdown on typical project

- Project to introduce new software for analysis of product release test data (SPSS syntax)

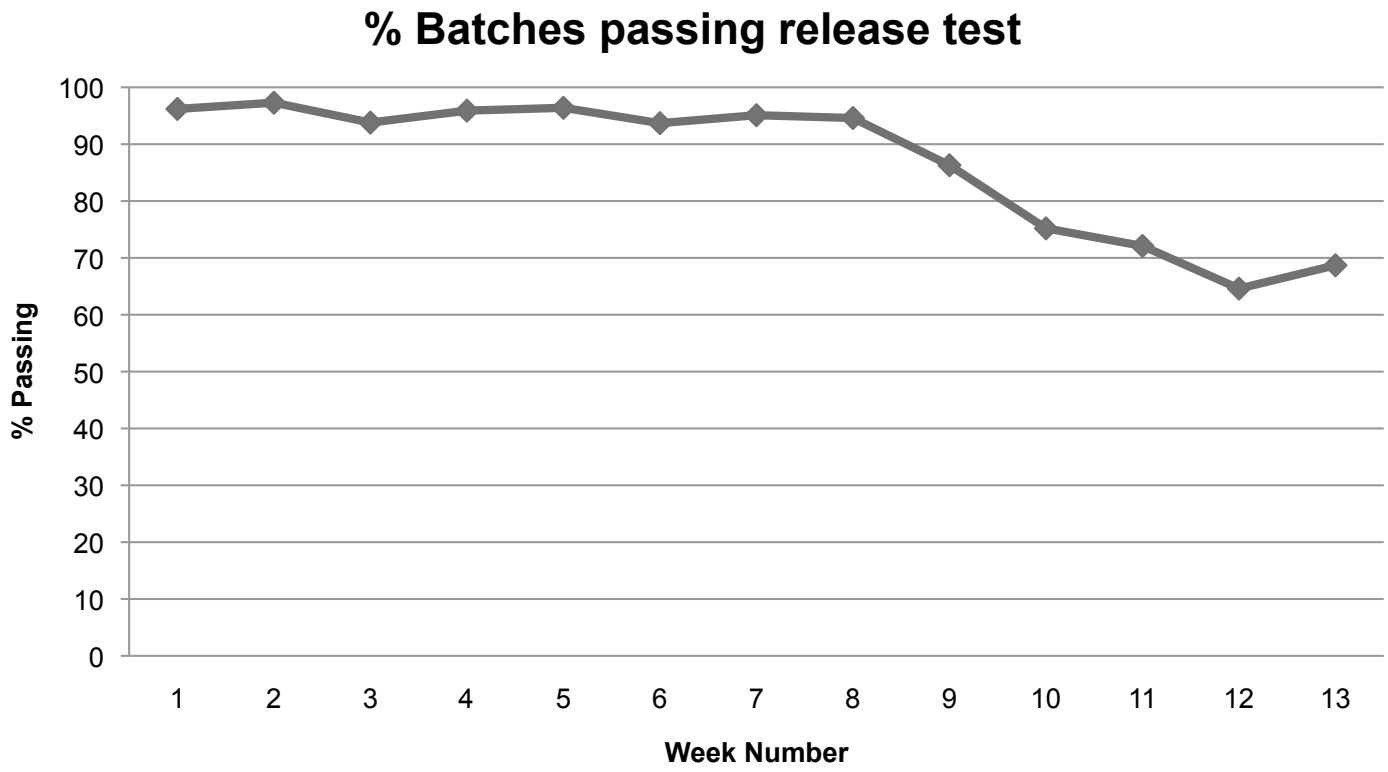


Other uses of SPSS at LifeScan

- Other uses of SPSS include
  - Analyses of clinical studies
  - Used in development of new products
  - Standard software for ad-hoc analysis by Statisticians and Data Analysts
  - Control charts within manufacturing process (early warnings)
  - Data mining for root cause investigations

Case Study 1

- Case Study 1 – Using SPSS to troubleshoot an issue and improve business yield
  - ❖ The problem: High Failure rates at release testing

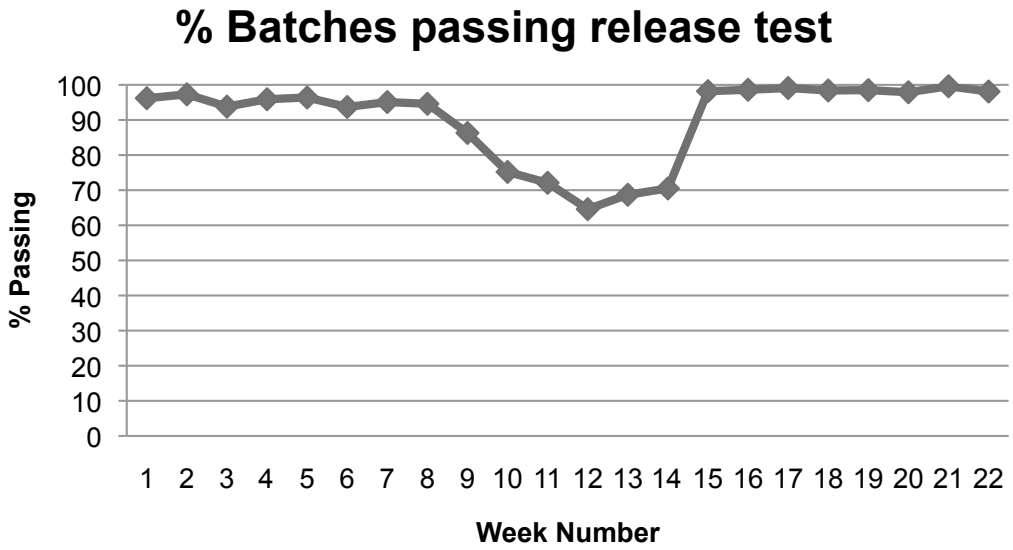


Case Study 1 (cont.)

- What happened?
  - Key factors identified and experimental designs formulated.
  - Experiments run and test results analysed.
  - Root cause identified and changes made to manufacturing process.
  - Updates made to data analysis programmes.
  - Data trended to ensure continued control of process.
  - **Problem fixed.**

Case Study 1 (cont.)

- The results:



Business	Customer
Higher yields = £/€	Less variability = more accurate results = better management of conditions

Case Study 2

- New product introduction
  - No coding
    - Customer = more accurate
    - Less testing steps, more accurate results
      - Less blood = less pain

Case Study 2 (cont.)

- High level project steps involving SPSS
  - Experimental Designs to assess optimal process settings
  - Analysis of data
  - Clinical study design and analysis
  - Setting of specifications for release test
  - Coding and validation of software (SPSS syntax) to release product and assess pass/fail

Common Statistical Techniques

- Some common statistical techniques used at LifeScan (typically programmed in SPSS)

Statistical Technique	Common Uses
(Linear) regression	Modelling of how strip result changes with increasing glucose concentrations
Tolerance Intervals	Assessing if product will meet accuracy requirements of external standards
Acceptance Sampling	Assessing output of production process against acceptable quality levels
Prediction Intervals	Assessments of product shelf-life
Operating Characteristic (OC) curves	Modelling of defect levels and lot acceptance
Control Charts	Trending and Monitoring of product performance and production data

Facts & Figures

- SPSS used over multiple manufacturing sites
- Two types of user
  - Advanced user – ad-hoc analysis and development of programmes
  - Core user – typically lab technicians who will run validated programmes, potentially multiple times daily
  - > 30 validated programmes (SPSS syntaxes) currently in use, all validated to 21 CFR Part 11 Compliance
  - Some programmes can be run up to 25 times a day over multiple sites, up to 5,000 times per year

Facts & Figures (cont.)

- Challenges (new versions, validation)
  - Must ensure all software runs on new version every time we upgrade, considerable effort involved

- Advantages of SPSS over other software
  - Cost, flexibility, specific chart types
  - Constraints imposed by multiple user involvement

Summary

- SPSS is a business critical application at LifeScan

- Every lot is assessed using SPSS software against quality requirements

- SPSS plays a key role in product quality and new product development

Questions?