

Company & Experiences

S5 provides expert statistical services mainly to the pharmaceutical industry, and in particular in the chemistry, manufacturing & controls (CMC) area. Services include planning of experiments, analysis and reporting of data, authoring and review of publications and regulatory documentation, and general statistical, strategic and development advice in particular for inhaled products.

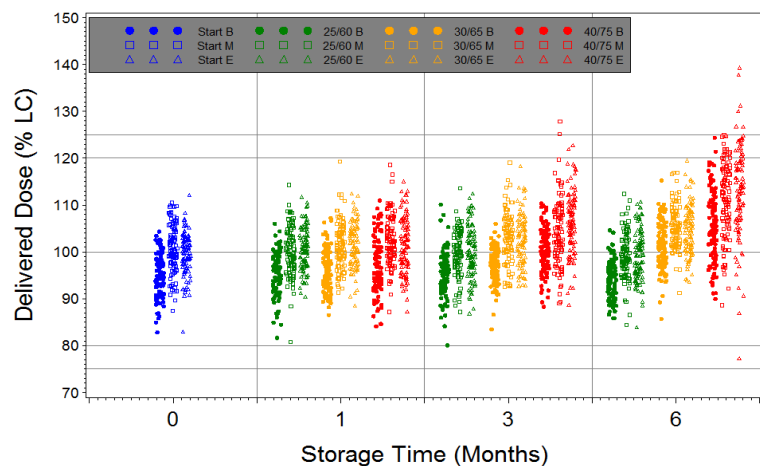
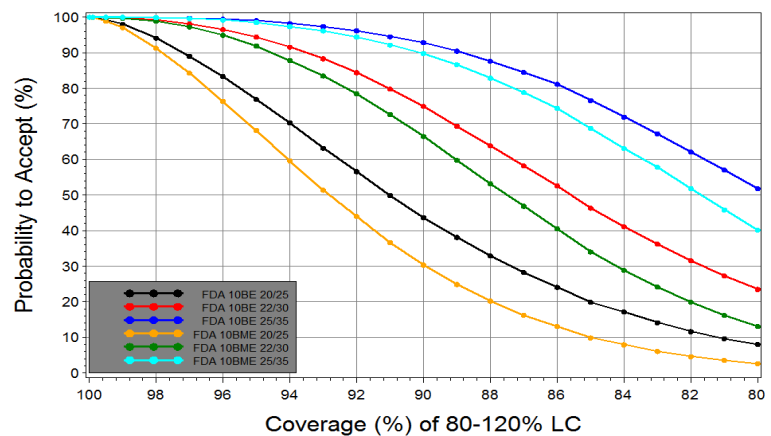
S5 is a private company owned and operated by Dennis Sandell, Fil Lic in mathematical statistics from the University of Lund, Sweden. Dennis has worked in the pharmaceutical industry since 1991 and provided statistical support and guidance in the CMC area since 1995. The main part of his career Dennis has worked in development and registration of different types of inhalation products, including DPIs, MDIs, nasal sprays and nebulisers. He has deep technical understanding of these delivery systems, used formulations and regulatory expectations for documentation. Dennis was the regulatory CMC statistics spokesperson for his employers, and has also represented these at conferences and in different international collaborations such as IPAC-RS, EPAG, PhRMA and PQRI. During 2004-5 he was member of the delivered dose uniformity sub-committee of the ACPS, and he is currently member of the USP Statistics Expert Committee and chair of the USP "Content Uniformity with Large Sample Sizes" Expert Panel. Dennis is adjunct professor at the Department of Pharmaceutics, University of Florida. He is author of 60 articles and co-author of the book "Problems and Snapshots from the World of Probability".

Expertise

- Device development
- Robustness / mis-use / in-use
- Device user study & inhalation profiles
- Formulation development
- Micronization / blending / spheronization
- Method development & transfer
- Automated / robotic testing
- Process validation
- Automated data checking
- Establishment of specifications
- Evaluation of stability data
- Justification of shelf life
- Stability out-of-trend
- Statistical process control (SPC)
- Adaptive control / release
- Process Analytical Technology (PAT)
- Quality by Design (QbD)
- In-vitro / NGI bioequivalence
- IVIVC & PK/PD modeling
- Clinical trial simulation

Main statistical approaches

- Design of experiments
- Hypothesis testing & ANOVA
- Modeling & simulation
- Multivariate analysis
- Regression & non-linear models
- Data mining
- Graphical presentation of data



Help us help others!

During 2011 – 2012 S5 has donated 5% of net profit to different projects supporting homeless people in Lund, and directly helped individual homeless with special needs. For 2013 - 2015 S5 will donate 5% of net profit to projects aiming to give children in difficult circumstances better possibilities to education.

Help S5 to help these children to a better future!