



2019 Analytics Solutions Conference Abstracts

Here is a preview of the talks you can look forward to attending during the June 19-20, 2019 ASC Conference in Minneapolis, Minnesota. Co-sponsored by Stat-Ease, Inc and Camo Analytics. <https://www.statease.com/asc-2019/>

Know the SCOR for Multifactor Strategy of Experimentation

Mark J. Anderson
Stat-Ease, Inc.

By way of example, this presentation lays out a strategy for design of experiments (DOE) that provides maximum efficiency and effectiveness for development of a robust process. It provides a sure path for converging on the 'sweet spot'—the most desirable combination of process parameters and product attributes. Whether you are new or experienced at doing DOE, this talk is for you (and your organization's bottom line!).



DOE: A Formulator's Perspective

William Arendt
Arendt Consulting

There is no doubt that statistically designed experiments can be the best approach used to optimize formulas and processes. This approach to project planning for formulation and process development is not new; it has been used for decades by scientists. The development of the software to utilize the design of experiments (DOE) approach from, initially, a main frame computer to the use with present day PC's is critical for the experimenter. This availability of software makes this approach to experimentation very viable. Formulation development is well understood, and the steps involved in the process are defined in most industries. But even today, experimenters and formulators still take the one step at a time approach to develop data. In the one step at a time approach, it is still difficult to account for the complex interactions of some ingredients in a formula or process without doing a very large number of experiments. A review of the steps involved in basic formulation approaches will be discussed. The use of DOE software to determine the number of experiments to produce formulas with optimal properties will be presented. Examples of designs as well as the results will be presented on how DOE can be effectively used.



Practical Considerations in the Design of Experiments for Binary Data

Martin Bezener
Stat-Ease, Inc.

Binary data is very common in experimental work. In some situations, a continuous response is not possible to measure. While the analysis of binary data is a well-developed field with an abundance of tools, design of experiments (DOE) for binary data has received little attention, especially in practical aspects that are most useful to experimenters. Most of the work in our experience has been too theoretical to put into practice. Many of the well-established designs that assume a continuous response don't work well for binary data yet are often used for teaching and consulting purposes. In this talk, I will briefly motivate the problem with some real-life examples we've seen in our consulting work. I will then provide a review of the work that has been done up to this point. Then I will explain some outstanding open problems and propose some solutions. Some simulation results and a case study will conclude the talk.



Design of Experiments in Chemistry: The Pitfalls

James Cawse

Cause and Effect

Getting the best information from chemical experimentation using Design of Experiments (DOE) is a concept that has been around for decades, although it is still painfully underused. In a recent article Leardi pointed this out with an excellent tutorial on basic DOE for chemistry. The classic DOE text “Statistics for Experimenters” also used many chemical illustrations of DOE methodology.



In my consulting practice within and outside GE for the past 30 years I have had many successes applying DOE techniques to solving difficult problems. In the course of these efforts, however, I have encountered numerous situations where “vanilla” DOE – whether from a book, software, or a “Six Sigma” course – struggles mightily because of the inherent complications of chemistry!

For example:

- In every experiment, chemists make mixtures of “stuff”. The underlying statistics of mixture designs has been fully developed by Cornell, but there are many instances where the system is subtly complicated.
- Virtually every chemical kinetics problem is nonlinear. Rates are functions of the product of concentrations and exponential in temperature.
- Modern catalyst systems are replete with 3-factor (and higher) interactions.
- “Numerical” factors can actually be functions of the choice of chemicals in the system.

In this talk I would like to introduce the reader to some of these complications and suggest ways to work with them. The real message, however, is that the experimenters must never take off their “chemist hat” when putting on a “statistics hat”!

Keynote: A Primer on Partial Least Squares Regression

Dennis Cook

University of Minnesota: Twin Cities

Partial least squares regression, which has been around for about four decades, is a dimension-reduction algorithm for fitting linear regression models without requiring that the sample size be larger than the number of predictors. It was developed primarily by the Chemometrics community where it is now ingrained as a core method, and it is apparently used across the applied sciences.



And yet it seems fair to conclude that PLS regression has not been embraced by some, even as a serviceable method that might be useful occasionally. Nor does there seem to be a common understanding as to why this rather enigmatic method should not be used, although bumptious discussions of PLS failings can be found in some applied areas. Perhaps this is as it should be — perhaps not.

This talk is intended as a relatively informal overview of PLS regression from a statistical perspective, including historical context, personal encounters, methodology, relationship to envelopes and, near the end, a few recent asymptotic results for high-dimensional regressions.

Keynote: Field Authentication and Adding Chemistry to Blockchain

Sharon Flank

InfraTrac



In a time where digital manufacturing transforms the flow of goods into a flow of data and raw materials brand owners need effective ways to secure quality and protect their products against counterfeiting. New technologies increase speed and quality in distributed manufacturing, but add complexity to the supply chain ... and possible security challenges. Intellectual property protection requires strategies to ensure that both the data and the goods are secure.

Non-destructive, speedy, and user-friendly field testing boosts both security and quality monitoring. New handheld instruments are cost-effective, especially when their capabilities are boosted with strong analytics. A blend of classic methods and new technologies using chemical tags, spectrometers and analytics provide protection for products threatened by counterfeiting, saving money and reputation.

This talk outlines the elements of the solution from the chemical “fingerprint” to field authentication using spectroscopy. This can be applied on pharmaceuticals, cosmetics, spare parts, electronics, wine and additive manufacturing, and the talk will include use cases and real-life examples. It will also touch on blockchain and when blockchain is helpful, and when it is just expensive hype.

Introduction of Hyperspectral Image Analysis for Quality Control

Geir Rune Flåten

Camo Analytics



Combination or fusion, of multiple data types can provide an improved description of a system, such as a production process. One can for instance use traditional process parameters to describe the physical properties of a process and complement this with chemical properties from a spectroscopic method. The two main challenges when combining multiple data sources in process analysis are i) synchronization and ii) scaling of the measurements. In the Camo Industrial Analytics platform, the data fusion challenges are resolved by Sample Alignment for synchronization and either block-scaling or dimension reduction for the scaling challenge. The challenges and opportunities for multi-sensor data fusion are discussed and it is shown how to successfully implement data fusion for process analysis and control.

Using Multi-Sensor Data Fusion for Process Analysis and Control

Geir Rune Flåten

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The importance of flexibility of multivariate PAT techniques

Eric Jayjock
Patheon



The application of multivariate PAT techniques, such as Raman and NIR, is an important aspect of continuous OSD manufacturing development. While on first inspection it seems reasonable to assume that the type of multivariate PAT instrument needed would be dictated by the process type (Direct compaction, dry granulation, wet granulation, etc.) However, in reality OSD products manufactured by any one pathway can be comprised of a multitude of different raw ingredients which can be combined in a wide range of different concentration depending on the formulation demands. The chemically unique nature of these materials means that the selection of the appropriate instrument may vary from product to product. At the same time the integration of a multivariate PAT instrument into a continuous manufacturing system can be expensive and time consuming. This talk will discuss the importance of incorporating a pathway for rapid integration of multivariate instruments into the continuous manufacturing platform for development of new products.

Optimizing the Vapor Deposition of Bioactive Films using Sequential Experimentation

Lou Johnson
JMC Data Experts



Researchers at the University of Pittsburgh are developing an external lung capable of exchanging O₂ and CO₂ in much the same way as a human lung. The exchange is achieved through a bioactive film deposited inside artificial capillaries by a vapor deposition process. The key functional characteristics of the film are its thickness which essential increases exchange capacity and the permeability of the film which improves its O₂ / CO₂ s transfer efficiency. Unfortunately, these two characteristics compete. Historical research had produced films with high capacity but poor transfer or thinner films with high transfer, but low capacity. The goal of this research was to thread the needle between these two competing responses to find compromise process conditions which would meet requirements for both characteristics.

The vapor deposition of process used to apply the film is a complex function of six input variables; electrical power, frequency and duty, reactant flow rate and pressure, and application time. The complexity of the process required a factorial approach to prioritize the main and interaction effects on the film's characteristics. Moreover, the reaction vessel was forever contaminated by the overflow of unreacted material and notorious for changing performance each time the vessel was cleaned and restarted. Center point runs during this initial experiment indicated strong curvature in the response requiring adding axial points to the original experiment to resolve the source of the curvature. The end results were unlike any seen before leading to a student/ advisor feud that still has not been resolved.

Developing an Assay for Screening Alzheimer's Inhibitors using Response Surface

Experimentation

Noah Johnson

University of Colorado, Denver



Alzheimer's disease (AD) is a progressive neurodegenerative illness caused by fibrillization (folding) of the amyloid-beta ($A\beta$) protein in the brain. Genetics that increase the risk for developing AD do so by carrying certain alleles of the apolipoprotein E (apoE) gene which act as a catalyst to accelerate the fibrillization rate of $A\beta$. Therefore, inhibiting this enzymatic process is a promising therapeutic approach to preventing AD. The goal of our research was to create an apoE4 / $A\beta$ assay that maximizes the fibrillization rate of $A\beta$ caused by apoE. The assay can then be used for high throughput screening of hundreds of potential inhibitors of this catalysis by comparing their reaction rate with that of the uninhibited assay.

Factorial experimentation was used to determine the best buffer, $A\beta$ supplier and reaction volume for our assay. Next, the effects of reactant concentrations on fibrillation rate was determined through a series of response surface experiments. Because of high error variation, this was more challenging than just a single central composite design. This talk will discuss tracing sources of variation to determine the appropriate sampling plan for the number of blocks, replicates and repeat samples within a replicate. Finally, since the assay procedure was prone to "botched" measurements, a rule of thumb for identifying outlier measurements was developed.

Improving collapsibility robustness of an EPS-CD by means of simulation and six sigma

Michal Majzel

ZF



Steering columns are one of the main elements of the passive safety restraint system in a passenger vehicle. The columns are designed to collapse in a frontal crash event generating an optimized ride down force to reduce chest and head injuries of the driver. This is a driver requirement when developing a new steering column design.

The steering column crash response is normally generated by several elements and interfaces, where many of them have also requirements in other functionalities in addition to passive safety. That results in a complex validation scenario of fusible and deformable elements, friction force contributors, all of them made of different materials (plastics, greased steel, casted aluminum components).

That multiple sources of variability is reducing the confidence in classic finite elements approach where normally the nominal and few best worst case conditions are considered for analysis, as well as from the real hardware testing side where that variability generates extra effort at the end of projects with a huge impact in the project costs and time (when few number of prototype parts are available). It is known that reality, especially when we are talking in the manufacturing field, there is a huge variability, and in that scenario the pass-fail criteria changes from a target value to a range of performance. This has been the main motivation when defining the scope of the project, "to bring manufacturing variability in the design process".

As part of ZF lean validation strategy a new method has been developed to improve the system robustness in ZF Active Safety division by means of virtual simulation and six sigma disciplines. The results obtained applying this new method are also applicable for a model-based development process and democratization.

In a nutshell the method starts with an analysis of variance of crash system response using a correlated virtual model, where the main parameters affecting the crash response are known (normally applicable after any new core development process). As a result of the analysis, it is obtained the regression equations of the system response.

As a second step, a Monte Carlo simulation has been applied using the equation obtained generating statistical results for a number of cases (based in the design tolerances) not manageable from the hardware testing perspective, neither

from the finite elements methods. In that project, the Monte Carlo simulation has been applied for 100 000 load cases generating probabilistic response instead of “deterministic response” (one geometry, one result).

With these two steps we have been able to create the manufacturing variability response for a destructive test in a highly cost and time effective approach. In addition, these equations have three more benefits equally or even more beneficial:

1. The equations define and quantify the importance of each factor, and consequently they can be used to generate a validation plan from component to system and enables to generate adequate component requirements as per a Model Based Development procedure
2. Democratization, the regression equation can be forwarded to designing team (or PLM tool), giving them an analytical tool for quick verification of main crash contributors.
3. Building customer confidence, as part of the democratization, the equation can be used during the requirement elicitation phase with customers generating confidence in the acceptance criteria.

Optimization of the Process Parameters for PLGA Microparticle Formulation Based on Taguchi Design

Rosemond Mensah

University of Hertfordshire

Poly lactic-co-glycolic acid (PLGA) is a synthetic polymer that has been widely studied and used in the formulation of microparticles (MP) for the controlled and sustained release of drugs. The single emulsion oil-in-water (o/w) evaporation technique is often used for the preparation of MP, but with many processing variables present, it is difficult to predict the size of particles formed. Particle size is a significant characteristic as it determines the profile of the drug release and dictates the potential routes of administration (e.g. topical or injection). Moreover, particle size is important with respect to tissue irritation. Some researchers have been able to identify several process parameters that can influence the formulation of microparticle by relying on trial and error method to achieve the desirable particle sizes. However, this optimization method is costly and inefficient, and a systematic approach based on design of experiments (DOE) is a better alternative method as it reduces the time and cost associated with the experiments. One of these DOE is Taguchi design which was proposed by Genichi Taguchi. Taguchi design is a statistical technique used to optimize parameters with complex interrelationship and its design protocol attempts to identify controllable factors that minimize the effect of “noise” (i.e. uncontrollable factors). Taguchi design exploits the use of orthogonal arrays (OA) to analyze many parameters with few experiments. The objective of this study was to employ Taguchi Level 12 and Level 18 OA designs to explore the effect of processing parameters on particle size using the single o/w evaporation technique. The parameters explored were: concentration of poly (vinyl alcohol) (PVA), molecular weight of PVA, concentration of PLGA, type of solvent (i.e. dichloromethane, ethyl acetate), concentration of PVA in the hardening bath, stirring/mixing speed, ratio of solvent/aqueous phases, emulsification rate, duration of speed and time for evaporation. The Taguchi design allows for a model to be developed to identify conditions leading to 10-50 μm MP for topical drug delivery.



PLGA MP were successfully fabricated using an established solvent evaporation technique. The median particle diameters were measured using a SympaTec laser diffraction particle size analyser (SympaTec GmbH, Germany). The L12 OA and L18 OA data were generated and analysed using Design-Expert software version 9 (Stat-Ease, Inc., USA). The first optimization step using the L12 design showed that all parameters significantly influenced the particle size of the fabricated MP with exception of concentration of PVA in hardening bath. In contrast, the L18 design results showed that molecular weight of PLGA does not significantly affect the particle size. The results from this study showed that application of Taguchi design can be used to understand the influence of parameters and predict the best combination of process parameters that can provide the optimal response condition- in this case, to formulate 10-50 μm MP for topical application.

Additional authors: Stewart B. Kirton, Michael T. Cook, Victoria Hutter, David Y.S. Chau

MVA and DOE: Throughout the Product Lifecycle

Chuck Miller
Camo Analytics



By now, there is plenty of evidence that both Multivariate Analysis (MVA) and Design of Experiments (DOE) are effective tools in the realization of improved process efficiency, cost savings, and improved quality assurance. Despite their proven effectiveness, many industrial users continue to relegate these tools only to special usage scenarios that are occasionally encountered during a product's lifecycle. This is unfortunate, as these tools, and the concepts supporting them, indeed have relevance throughout the lifecycle of a product. This presentation will demonstrate the value of MVA and DOE tools and concepts throughout the lifecycle of a product: from early discovery through long-term support of commercial production. Several industrial project and product case studies will be used to illustrate this argument, including an on-line NIR application that has been in continuous operation for about 30 years. Through these case studies, I hope to demonstrate the persistent value of not only DOE and MVA tools, but also the philosophies behind them, to improve probability of success.

PAT Best Practices: Learnings Across Industries

Chuck Miller
Camo Analytics

It has been approximately 15 years since the US FDA released its Process Analytical Technology (PAT) Guidance for the pharmaceutical industry. Since then, the general consensus has been that adoption of PAT in pharma has been begrudgingly slow, yet significant. Several possible causes of this slow uptake have been proposed, and these have ranged from cultural, organizational, financial and regulatory issues. In the meantime, it could easily be argued that "Process Analytical Technology" has been effectively exploited since the early 1940's: starting in the chemicals industry, and expanding to the food, agriculture and petrochemical industries through the 1970's and 1980's. In fact, these industrial sectors contain some of the most enduring and value-adding process analytical applications, with several of them spanning more than 10 years in operation. These successes would seem to support the notion that the technology of PAT is inherently able to provide value, provided that best practices are used to implement them. The purpose of this presentation is to compile a set of PAT best practices, borrowing from a wide array of industries. It will be shown that each industrial sector has made unique and strong contributions to PAT practices over the years, thus putting this technology in a good position to exploit further technological advances in optics, electronics, computing and data science.

Using Experimental Design and Statistical Software to Investigate the Impact of Amines on Metalworking Fluid Lubricity

Jason Pandolfo
Quaker Chemical



Amines are an important chemical functional group for metalworking fluid formulations. As bases, amines will react to neutralize fatty acids and other acidic components in a product. They also provide additional performance benefits such as pH buffering and corrosion resistance.

A minor modification to a metalworking fluid showed worse lubrication performance even though the lubricity drivers were not changed. An investigation was conducted using experimental design and Design-Expert® software to identify what was causing reduced lubricity in the product. The results indicated that a change in the amine package was the source of the problem.

Further experimentation was performed with mixture designs to gain a better understanding of amine impacts on metalworking fluid machinability. The results showed that both the individual amine species and the total level of amine in the product can have a significant effect on lubricity. A lasting benefit of this work is a design model that can be used by formulators to choose optimal amine packages for a product.

How to Increase Design of Experiments Success

Carol Parendo
Collins Aerospace



In this session, we will look beyond the math and delve into several tips for successful Design of Experiments (DOE) execution. The speaker will share her real-life stories in order to bring these tips to life. Through these stories, you will understand that these tips may make all the difference between completing a DOE and having DOE results that are impactful. Learn these tips and you will be more impactful with your DOEs.

Examples of tips to be discussed:

- Choose variables far apart (within reason) for initial experimentation.
- Understand assumptions and limitations while setting up a DOE.
 - Confounding variables/interactions (alias structure)
 - Independent variables, ability to change variables
 - Continuous vs. Discrete variables/responses
 - Be aware of potential or expected curvature and distribution
 - Feasibility of randomization and strategically randomizing
 - Additional data to gather (monitoring or holding “noise” constant, lots of materials).
- DOE is typically most effective as an iterative process. As a rule-of-thumb, less than 25% of the effort (hours, \$) should be on the first experiment.
- You may need to be creative in breaking the problem down to achieve schedule, cost, and technical goals.
- If analysis has issues, check for typos, review experiment comments, consider anomaly (in part, process, or test, run order vs. std order). Don't just delete the offending run!

Text Mining: Discovering Themes in Text Records

Paul Prew
Ecolab



Computing power and clever algorithms have enabled pattern-searching in huge collections of ‘unstructured’ text data. The goal is to surface the predominant words, phrases, and even themes that are buried in the text. At the simplest level, moving windows go through the text, cataloging words and phrases which are then ranked by count. At a deeper level, data mining techniques - clustering is a popular choice - are also applied to identify themes or topics that “drive” the creation of the text.

One of Ecolab’s largest businesses provides soaps, sanitizers and dishwashing equipment to restaurants. Servicing the products is part of the contract. Customers can request on-site service from one of the thousands of service specialists throughout the U.S. A recent project was undertaken to analyze these calls, and use the knowledge gained to inform the next generation of products. To that end, text mining has been applied by Ecolab’s statisticians to the call center records. For this presentation, an introduction to text mining will be made in the context of analyzing tens of thousands of service calls from restaurant kitchens.

Analyzing Experiments Involving an Amount Factor with a Zero Setting

Howard Rauch
Eastman Chemical



An experimenter wants to view the effect of different amounts of an additive on final properties of a formulation. The experimenter also wants to check for any effects due to two different suppliers of the additive (for example, suppliers A and B). A full-factorial experiment comprised of two factors – additive amount and additive supplier – could be designed to meet these needs.

However, an issue occurs if the experimenter wants to set the low level of the additive amount to zero. In this situation, two of the combinations in the factorial experiment will have no additive and would therefore be identical formulations, even though one formulation is labeled “Supplier A” and the other formulation is labeled “supplier B.” This amount-at-zero issue can complicate the data analysis.

Pat Whitcomb of Stat-Ease has addressed this problem in the realm of mixture experiments, but this problem can occur in non-mixture experiments as well, as demonstrated by this additive experiment example. The amount-at-zero issue can even occur in manufacturing process experiments. For instance, time could be an “amount” factor that could be set to zero for some runs in a process experiment.

Formulation and process examples will be presented to make experimenters aware that this amount-at-zero issue can occur in relatively simple designed experiments. The various problems resulting from the amount-at-zero issue will be discussed. Finally, strategies for analyzing and modeling data from these types of experiments will be offered.

Multivariate analysis: From chemometrics modeling to process monitoring

Sylvie Roussel
Ondalys



Using chemometrics offers a faster and more precise assessment of composition, physical, and sensory properties of a product, and the adoption of chemometrics is finding ever widening applications across many different industries. Chemometrics use multivariate methods to extract information by data-driven means to develop models that can be deployed in a process environment for real-time prediction of end-product properties to ensure every product sent to market meet the required properties. Typical modelling approaches include the use of data mining, machine learning, spectroscopic calibrations, sensor fusion & multiblock analysis and Design of Experiment (DoE/QbD). Through customer projects the challenges and opportunities using different modelling approaches are discussed and it is shown how to successfully use sensors and chemometrics for process monitoring.

Strategically Delivering Advanced Automated Process and Release Analytics Direct to Clients: The Benefits of the CDMO

Pankaj Sinha
Lonza



Lonza is an integrated solutions provider that creates value along the Healthcare Continuum®. Through our Lonza Pharma Biotech & Nutrition segment and our Lonza Specialty Ingredients segment businesses, we harness science and technology to serve markets along this continuum.

Patients and consumers benefit from our ability to transfer our pharma know-how to the healthcare, hygiene, fast-moving consumer goods environment and to the preservation and protection of the world where we live. As our PAT initiative has identified deliverable synergies with business-unit manufacturing operations, advanced analytics has begun emerging from the research labs to client deliveries. However, within regulated manufacturing the paradigm shift of computerized learning in Industry and Pharma 4.0 has much greater risk than automations and predictive power in

consumer electronics and finance. By working together with CAMO Analytics and delivering advanced analytics in optimizing commodities consumer product manufacturing, we have designed drop-in analytics platforms that we are able to mitigate risks in automations of pharmaceutical and biologics products. These platform analytics solutions delivered forefront and consistently throughout the product and process development lifecycle reduces cycle times in market delivery.

PAT in pharmaceutical formulation manufacturing

Angela Spangenberg
DisperSol



From a research collaboration with the University of Texas at Austin the KinetiSol®-process emerged as an innovative technology for the production of pharmaceutical amorphous solid dispersions, in which the crystal lattice of a poorly-soluble drug is broken, rendering amorphous drug molecules dispersed in pharmaceutical polymers in order to enhance bioavailability and boost solubility. At-line process monitoring using Raman spectroscopy enables quality control within seconds of manufacture to ensure the absence of residual crystalline drug and impurities. The overarching goal is to use rapid spectral analysis in order to control the process itself and terminate each mixing event at precisely the right time, without over- or under-processing. In this presentation the setup of the system to enable the real-time process will be presented together with some early stage results and experiences.

Solving Complex Problems

Dr. Geoff Vining
Virginia Tech



Organizations face increasingly complex problems that are critical to their operation and, in some cases, for their survival. Such problems require the proper use of data and its interpretation. A major issue is how to develop appropriate solution strategies to develop good solutions efficiently and effectively.

Historically, data analysis focuses on tools: design of experiments (DOE), regression analysis, statistical process control, modeling. More recent tools form the foundations for analytics and data science. Tools are important for creating good solutions to complex problems. However, it is crucial to understand “the right tool, for the right job, at that right time, correctly applied.” Today, there are too many people who claim that their tool is the universal solution. The reality is more complex.

This talk outlines the new discipline that is devoted to the art and science for creating good solutions for complex problems using data. The paradigm for this new discipline is chemical engineering. Chemical engineering builds upon both chemistry and mechanical engineering to create new chemical processes and to improve existing chemical processes efficiently and effectively. Crucial to these solutions is the concept of “unit operations”. Chemical engineering theory focuses on understanding these core operations and how to develop proper strategies to deploy them. Our new discipline, statistical engineering, takes such an approach to the complex problems facing organizations today.

This talk introduces at a high level this new discipline. It then outlines the important roles that both DOE and analytics play in the solution of complex problems. In the process it emphasizes the importance of strategy and understanding exactly what the tools can and cannot do.