

# SAFETY BY DESIGN FOR DRUG DELIVERY DEVICES

**SCHERDEL**

**Professor Stefan Schreiber** of **Technische Hochschule Würzburg-Schweinfurt**, **Dr Theo Wember** of **camLine** and **Sebastian Block** of **Scherdel Medtec** discuss how using Design of Experiments methodology can provide insights into the manufacturing process of power springs that can enable manufacturers to more robustly control variables and produce more consistent outputs.

Scherdel Medtec is an expert in metal components for drug delivery devices, manufacturing precision parts for the drive and dosing systems used in autoinjectors, pen injectors and inhalers, where ensuring correct and safe functionality is essential for patient safety. For this reason, Scherdel places a strong emphasis on product quality. Potential influences on functional performance can be evaluated at an early stage using a Design of Experiments (DoE) methodology, including for effects originating from material suppliers. This enables an optimal process setup and a clearly defined set of process parameters that can reliably prevent deviations from product specifications.

## POWER SPRINGS

Developing a power spring is a demanding, multistep process. Experienced development engineers can easily identify 20 or more parameters that influence key performance characteristics. However, not all of these parameters – particularly those derived from material properties – can be controlled during manufacturing. Understanding the interactions between these factors is

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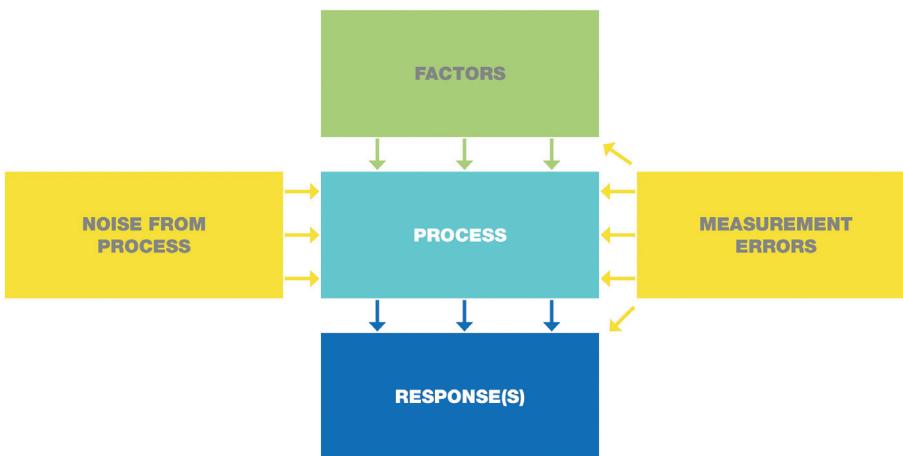


Figure 1: Process model.

therefore essential to achieving consistent and optimal product quality. This is where DoE provides significant value.

Figure 1 shows the process model used throughout the DoE framework. In this model, the manufacturing process is ideally influenced by controllable factors (green), which lead to the desired responses (blue). Noise effects (yellow) represent stochastic influences originating from upstream processes or the measurement system. DoE provides objective evidence of how production is affected by noise and how robust process windows can be established to maintain consistent performance.

#### Winding Process Manufacturing

Before applying DoE, it is necessary to understand the many aspects of the manufacturing process. Although the fundamental theory behind power springs

is widely accessible, the complexity of the manufacturing sequence makes it impractical to create a comprehensive analytical model of the entire process. In particular, friction between loaded and unloaded coils cannot be represented by analytical equations reliably.

Power springs are typically manufactured through a winding process using an austenitic stainless-steel strip of specified width and thickness. Several factors influence the quality, function and reliability of the final product. Key steps of the process include:

1. **Supplied Materials:** For this type of spring, Scherdel typically uses cold-rolled steel strips with predetermined technological parameters, such as tensile strength, chemical composition and geometric properties, all defined in close co-ordination with suppliers.

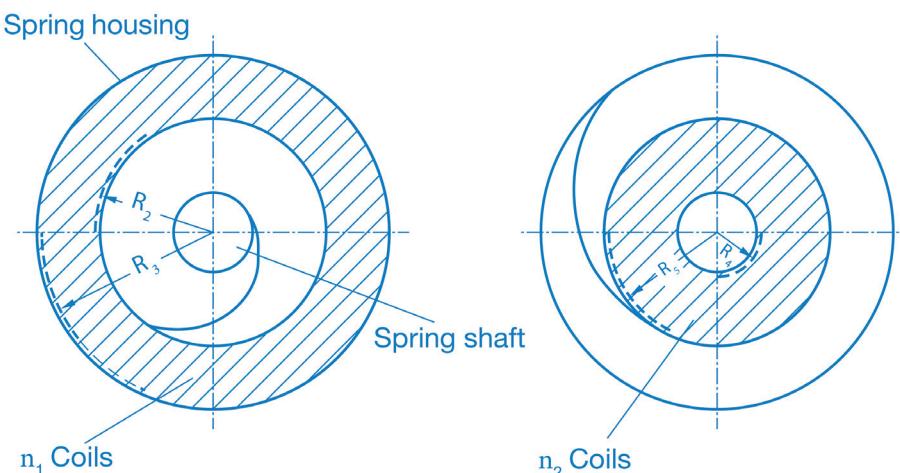


Figure 2: Geometry of a power spring.

2. **Cold-Forming:** Various spring designs used in medical devices, such as torsion springs or power springs, are formed using dedicated cold-forming machinery. Relevant factors include machine-specific settings and the condition of tooling (predictive maintenance).

3. **Heat Treatment:** Heat treatment affects cold-setting behaviour and tensile strength. Important parameters include oven temperature, tempering duration and possible positional effects within the oven.

4. **Assembly:** Depending on the specific spring design, an assembly step may be required. Scherdel can provide complete drive systems, including housing, directly to customers.

5. **Quality Control:** Customers typically specify the required force or torque values. Additional dimensional or functional requirements may also apply. Scherdel treats measurements as its own process and works to minimise measurement variation to ensure the highest possible consistency.

#### The Equations Behind Power Springs

According to the established “spring manual” (available upon request from Scherdel Medtec), the torque  $M_T$  of a power spring without coil clearance is defined as:

$$M_T = \frac{E \cdot b \cdot t^3 \pi (n_2 - n_0)}{6 l_w}$$

- $E$ : Young's modulus of the material
- $b, t$ : Width and thickness of the strip
- $n_0, n_2$ : Number of coils in the spring's released and fully loaded status
- $l_w$ : Spring length is defined as:

$$l_w = (R_2 + R_3)\pi \cdot n_1 = (R_4 + R_5)\pi \cdot n_2$$

With  $n_1$  as the number of coils in an intermediate loading and  $R_2$  to  $R_5$  as the radii defined in Figure 2.

Figure 3 presents a simulated torque-angle curve illustrating an exemplary requirement of 35 Nmm at the beginning and 30 Nmm at the end of use over 10 revolutions (3600°). The torque drops to zero in the 11th revolution, indicating full release. The complexity of this

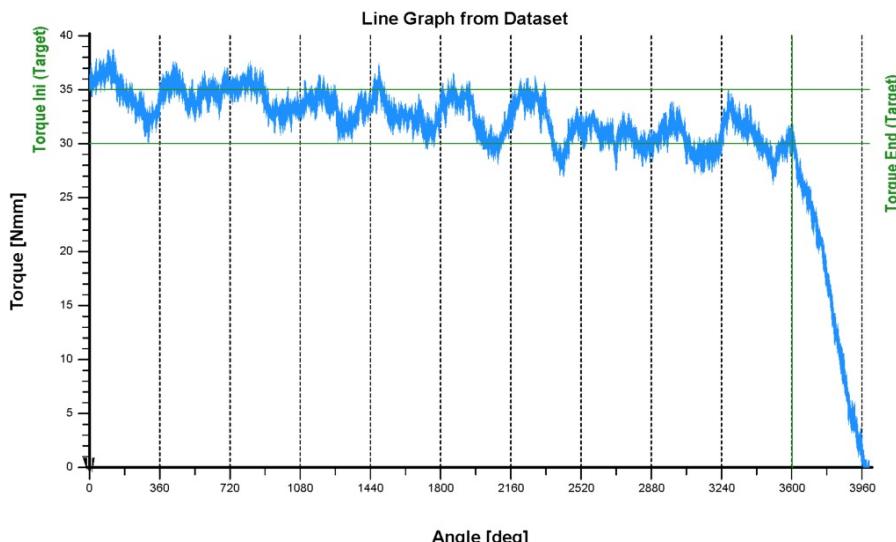


Figure 3: Exemplary simulated torque versus angle diagram of a power spring used in the DoE analyses.

behaviour and the many interactions within the production process demonstrate the necessity of a structured DoE approach.

## DESIGN OF EXPERIMENTS

From more than 20 possible identified factors, six were selected for the study. Three factors and their respective ranges are disclosed, while the further three

( $x_4$  to  $x_6$ ) remain confidential (Table 1). The investigation focused on the winding process. The responses reflect the initial torque, end torque and one additional undisclosed parameter (Table 2). The DoE methodology is a tried and tested sequence of preparatory works and in-depth mathematical analyses beyond the scope of this text, so only a rough sketch is covered here.

Factors	Symbol	Min	Max	Units
Coil Thickness	Thickness	95	105	µm
Tempering Temperature	Tempering Temp	340	420	°C
Tempering Time	Tempering Time	30	40	min
-undisclosed-	$x_4$			
-undisclosed-	$x_5$			
-undisclosed-	$x_6$			

Table 1: List of factors.

Responses	Symbol	Goal	Low	High	Target	Units
Initial Torque	Torque Ini	Target	30	40	35	Nmm
End Torque	Torque End	Target	25	35	30	Nmm
-undisclosed-		Maximise				

Table 2: List of responses.

Using engineering reasoning and the theoretical background of power spring behaviour, a polynomial model was created linking all six factors to the three responses. The model contained 26 coefficients, representing the minimum number of required experiments. The full “design space” of the six factors would require 324 experiments. Using a D-optimal design, a practical subset of 32 experiments was selected.

Each experiment was carried out ten times, resulting in a total of 320 observations. While this number is only slightly less than the aforementioned 324 experiments, repeating a single experiment ten times only requires a fraction of the effort of performing 10 different experiments. After the experiments were executed and analysed, the model for the response “Initial Torque” achieved an adjusted  $R^2 = 0.89$ , indicating that 89% of the observed variation is explained by the model – an excellent result.

One of the most notable findings was the interaction between coil thickness and factor  $x_5$ , shown in Figure 4. Although coil thickness was a controlled factor in the experimental setup, it becomes an uncontrolled noise factor during real production because it is defined by the supplier. The interaction plot shows that at the minimum level of  $x_5$ , the impact of coil thickness variation is significantly reduced and the curve becomes flatter. Thus, the process becomes more robust. This is a key principle of Taguchi’s robust design strategy<sup>1</sup> – use controllable factors to minimise the influence of uncontrollable ones.

**“THIS IS A KEY PRINCIPLE OF TAGUCHI’S ROBUST DESIGN STRATEGY – USE CONTROLLABLE FACTORS TO MINIMISE THE INFLUENCE OF UNCONTROLLABLE ONES.”**

### Interaction Graph for Torque\_Ini

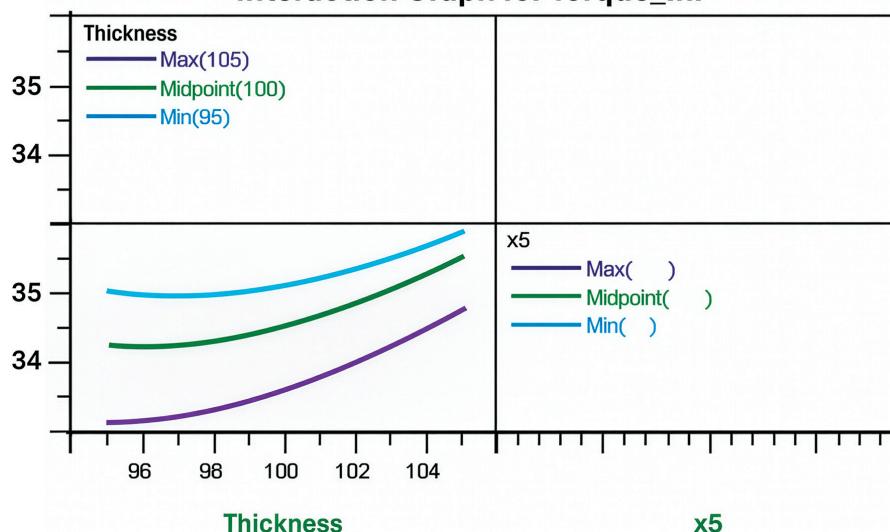


Figure 4: Interaction Graph for initial torque.

After this investigation, the statistically proven models for all three responses constitute the ultimate toolset for finding good process parameters and identifying appropriate corrective measures in case of process deviations.

#### A MATTER OF DESIGN

As in many production processes, the large number of controllable and uncontrollable factors presents both

opportunities and challenges. To achieve stable production while meeting stringent quality requirements, all contributing factors must be understood and controlled. The authors strongly recommend implementing a rigorous quality-assurance strategy based on DoE. As demonstrated, DoE reveals valuable insights into system performance – insights that would otherwise remain hidden. When beneficial interactions such as the one between coil thickness and factor  $x_5$  are identified,

**"FOR SAFETY-CRITICAL COMPONENTS, ESPECIALLY THOSE USED IN DRUG DELIVERY DEVICES, SAFETY MUST BE A MATTER OF DESIGN, NOT A MATTER OF CHANCE."**

the resulting improvements in process robustness can be substantial.

Such findings would rarely be discovered without a systematic approach. For safety-critical components, especially those used in drug delivery devices, safety must be a matter of design, not a matter of chance. DoE offers a powerful methodology to reduce costs and accelerate time-to-market using a minimal number of trials while maximising insights.

#### REFERENCE

1. Taguchi G, "Introduction to Quality Engineering: Designing Quality into Products and Processes". Asian Productivity Organization, Jun 1986.



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Professor Stefan Schreiber, PhD, studied general mechanical engineering at the Technical University Darmstadt (TUD) in Germany, completing a PhD in the field of biomechanics at the TUD Institute of Mechanics. During his career in industry, he managed the testing and metrology department of a distinguished German original equipment manufacturer. Professor Schreiber was appointed to a professorship for General Mechanical Engineering at the Technical University of Applied Sciences Würzburg-Schweinfurt (Germany) in 2010 where he teaches Engineering Mechanics, Machine Dynamics, Fatigue and Design of Experiments.

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Theo Wember, PhD, has been working as a freelance statistician since 1988. His main focus is on Design of Experiments but he also works in other areas of technical statistics, including reliability engineering, sensitivity analysis, Monte Carlo simulation, root cause analysis and process data analysis. In the last decade, all these challenges have merged into machine learning projects. He spends a significant part of his working time on training, which is often followed by customer projects. He also performs general project work with a focus on technical statistics in German and English.

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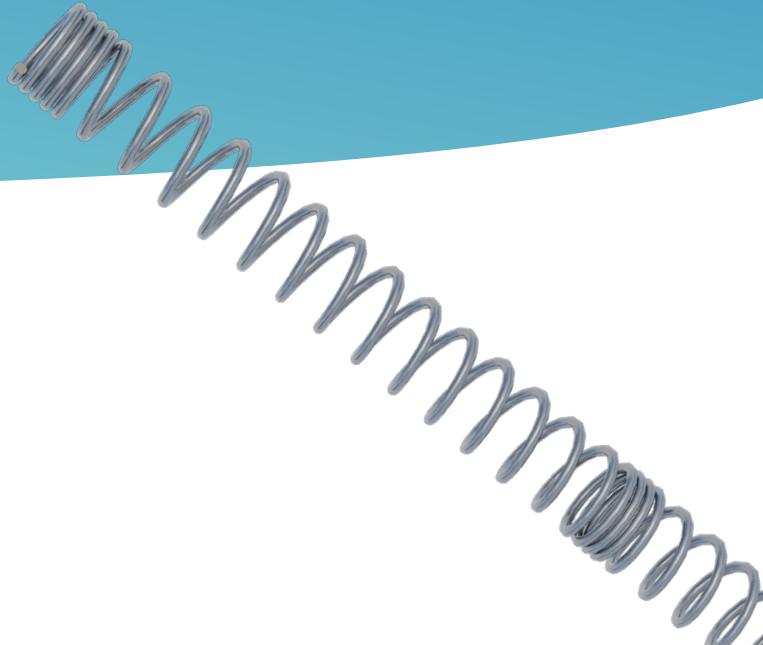
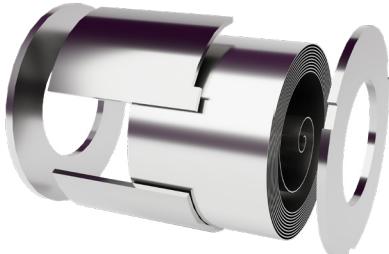
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