# "Validating the Laser Welding Process, A Case Study"

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## Introduction

The laser welding world encompasses a wide range of applications and part sizes. Within this unique world, competition for securing new orders and retaining existing business is always increasing. One way to provide a competitive edge is to validate your laser welding process. The automotive and medical device sectors have a long history of using the validation process. To ensure consistent laser weld quality, the automotive companies require proof of laser welding validation from their automotive sub-system suppliers. In addition, the Federal Food and Drug Administration (FDA) requires medical device manufacturers to validate processes used to manufacture a medical device. Both sectors essentially employ the same validation process, but use different labels for each validation component.

This article illustrates the necessary steps and highlight considerations to successfully validate the laser weld process.

## Validation and Verification Definitions

The terms *validation* and *verification* are often used interchangeably, but have very different meanings. *Validation* ensures that the right product was made. *Verification* ensures that the product was made right. FDA 21CFR820.3 provides the following detailed definitions:

*Validation* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fullfilled[1].

*Verification* means confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled[2].

*Process Validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications[3].

## Why Validate?

There are four major reasons for validating the welding process:

*One*, for Six-Sigma oriented manufacturers, there is no laser weld monitor or checker on the market today that can separate bad welds from good welds to a six-sigma confidence level. The only known means of determining weld quality without destroying 100% of the finished product is to validate the laser welding process.

*Two*, for medical device manufacturers, the FDA mandates that manufacturing processes that cannot be fully verified must be validated as part of the company's Quality System Regulation (QSR)[4].

*Three*, the improvement to process yield through the reduction of product scrap and field failures far outweighs the cost of validating the laser welding process.

*Four*, validation is a good marketing tool. Manufacturers capable of proving their laser weld quality level to their customers have a substantial advantage over their competition.

## Validation Components

The validation process consists of six main components, beginning with the Validation Plan(VP) and ending with the Product Performance Qualification (PPQ). See Figure-1. Each component contains its own protocol, data, and reporting documents. Manufacturers may implement these six steps in different ways to accommodate their own unique design and manufacturing processes. A common modification incorporates the Equipment Installation Qualification (IQ) with the Equipment Operational Qualification (OQ). Another variation includes the Design of Experiment (DoE) process as part of the Equipment Operational Qualification (OQ) instead of the more traditional method of incorporating the DoE into the Process Qualification (PQ). In either case, the goal is the same; to consistently produce a product that meets the intended product use.

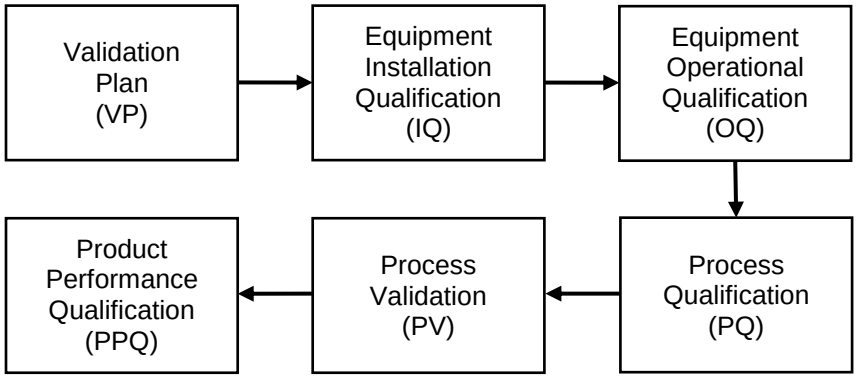


Figure 1 – Validation Components

## Laser Welding Validation Example

While this article uses a minimally invasive surgical tool to illustrate the laser welding validation process, this basic validation process applies to all laser welding applications. The surgical tool shown in Figure-2 consists of two parts: a) Tip and b) Shaft. Both parts are made from 304L stainless steel. The Tip must be inserted into the Shaft without cocking the Tip or damaging the Shaft side wall. The insertion process must minimize the weld junction gap between the Tip and Shaft. A gap in the weld junction can cause voids and expulsion.

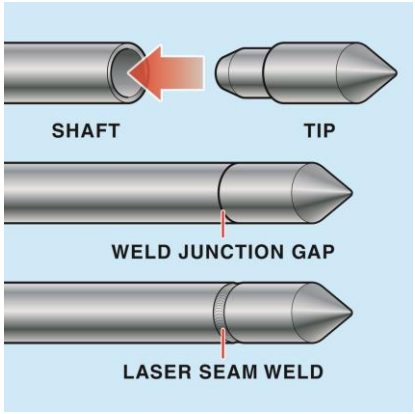

Figure 2 - Surgical Tool Assembly and Laser Seam Weld

Previous laser welding studies involving this application have shown that the laser welding process can tolerate a weld junction gap of 0.05-mm maximum. The mechanism used to insert the Tip into the Shaft is part of the laser welding system. Therefore, the ability to consistently assemble the Tip and Shaft with a weld junction gap of less than 0.05-mm must be verified as part of the validation plan (VP). For this application, the required fit-up study is included in the Equipment Operational Qualification (OQ) validation component.

## Validation Plan (VP)

All validation processes must start with an overall plan called the Validation Plan (VP), also known as the Validation Master Plan (VMP). This plan must address each of six key elements shown in Figure-1. A well-conceived Validation Plan is a road map to success. It is important to note that the VP is not a linear process, but rather an iterative process. As each element of the Validation Plan is developed and tested, the VP will need updating to reflect the actual validation process.

Validation plans differ between industry sectors such as the medical device and automotive industries, but have the same basic components. Validation protocols also differ between manufacturers within the same industry sector. Figure-3 contains a comparison between the medical device and automotive sensor manufacturing validation steps.

| Medical | | Automotive | |
|---|---|---|---|
| Installation Qualification | IQ | Equip Set Up | - |
| Operational Qualification | OQ | Equip Dry Run | - |
| Process Qualification | PQ | DoE<br>Optimization<br>Confirmation | MQ1.0<br>MQ1.5<br>MQ2.0 |
| Process Validation | PV | Confirmation | R-R |
| Performance Qualification | PPQ | Environmental Tests | P-PAP |

Figure 3 – Validation Steps, Medical Device and Automotive Sectors

## Equipment Installation Qualification (IQ)

Equipment Installation Qualification (IQ) involves setting up the equipment in accordance with supplier installation drawings and specifications and verifying equipment calibration. Repeat the IQ after moving or relocating equipment. Replacing or repairing a key component or sub-system may also require repeating the IQ[5]. Revalidation criteria are typically contained in the Validation Plan (VP). Equipment manuals contain the key installation information required to ensure proper equipment operation. The IQ can be a single document that includes the protocol, data, and report. For very simple equipment installations, the IQ is often included as part of the Equipment Operational Qualification (OQ). Sample IQ elements required to ensure equipment functionality include:

1. Mains voltage range.
2. Mains frequency range.
3. Air flow space for adequate cooling.
4. Room temperature range.
5. Minimum bend radius on the fiber optic cable connecting the laser power supply to the focusing head.
6. Argon cover gas flow system.

It is very important to perform a calibration check at the beginning of the laser welding validation process. This step may be as simple as verifying the information on a calibration certificate from the laser welding equipment supplier to ensure that the welding equipment is still in calibration. Some six-sigma manufacturers insist on performing their own calibration check at the beginning and end of the validation process. For those manufacturers performing their own calibration measurements, use calibrated test equipment that is traceable to a known standard and has a resolution that is twice the smallest resolution of the measured parameter.

## Equipment Operational Qualification (OQ)

Equipment Operational Qualification (OQ) verifies that the laser welding system meets the manufacturer's performance specifications. The OQ also establishes procedures and record keeping for equipment calibration, cleaning, operation, maintenance, and operator training. Equipment manuals contain the key specifications regarding equipment capability. Repeat the OQ after moving or relocating equipment. Replacing or repairing a key component or sub-system may also require repeating the OQ[5]. Revalidation criteria are typically contained in the Validation Plan (VP).

For laser welding systems, the most important welding equipment parameters are weld power, pulse duration, spot size, pulse repetition frequency, which controls weld spot overlap, and weld spot location in all 3-Axes of the laser welding system. Verify that the entire welding system produces the programmed laser welding parameter power over the projected operating ranges on a repeatable basis and append the data to the OQ report. In the automotive sensor industry, the OQ may also involve operating an automatic welding station without weld energy or parts for a 24-hour "dry run".

Many laser welds are very sensitive to the weld junction gap (fit-up) and the weld spot location on the weld junction in all three axes, X, Y, and Z. The laser weld shown in Figure-2 is no exception. Therefore, Gage R&R studies must be conducted on the laser welding system to establish capability for both the weld junction fit-up and weld spot position. Use three operators to conduct the Gage R&R studies. For the surgical tool example shown in Figure-2, the maximum range data from all three operators were compared against the maximum range limit values. If available, use historical data from similar laser welding processes to set limits. If historical data is not available, then determine limit values using the Design of Experiment (DoE) process. For this example, the maximum range limits for both the weld junction gap and weld spot location were derived from historical data.

***Gage R&R Study Results – Weld Junction Fit-up***

Maximum Range Limit Value= 0.050-mm

Actual Weld Junction Fit-up (Gap) Range = 0.025-mm < 0.05-mm, passed

***Gage R&R Study Results – Weld Spot Location*, worst case range value**

Maximum Range Limit Value = 0.30-mm

Actual X-Axis (Shaft Axis) Range = 0.09-mm < 0.30-mm, passed

Actual Y-Axis (Shaft Diameter) Range = 0.06-mm < 0.30-mm, passed

Actual Z-Axis (Laser Focus) = 0.09-mm < 0.30-mm, passed

For the surgical tool example, both Gage R&R studies successfully established the fit-up and laser weld spot positioning capability.

## Process Qualification (PQ)

The Process Qualification (PQ) follows the OQ and contains seven sub-components as shown in Figure-4.

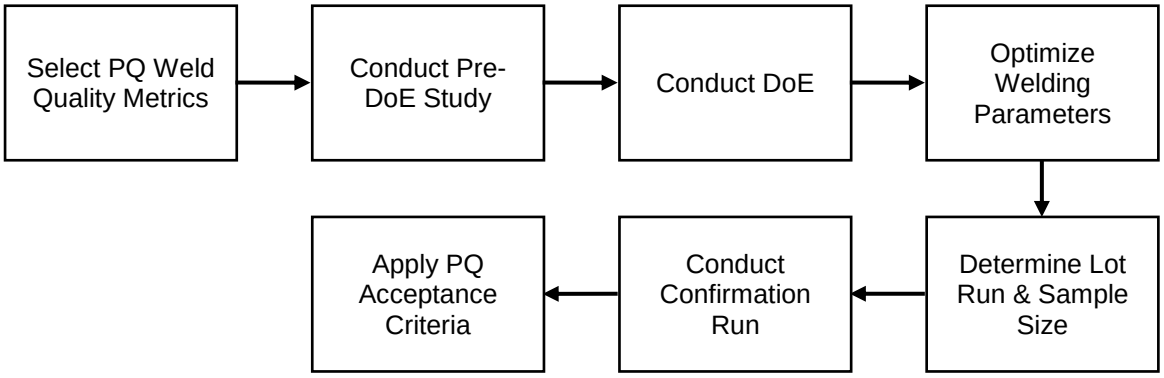


Figure 4 - PQ Components

***Select the PQ Weld Quality Metrics***

PQ begins with selecting the weld quality metrics, which should represent the stresses and physical limitations subjected on the final laser welded product by the end user. This surgical tool is pressurized during the procedure and must be free of voids, even if the voids do not leak. For this example, two PQ weld quality metrics were selected: a) minimum burst pressure and b) absence of voids.

Measuring burst pressure is time consuming, expensive, and destructive. Therefore, it was decided to add two non-destructive metrics that might correlate with the burst pressure: a) weld spot location in relation to the weld junction centerline and b) weld width.

***Conduct the Pre-DoE Study***

The purpose of conducting a pre-Design of Experiment (DoE) study is to:

1. Select the variable input factors.
2. Fix certain input factors.
3. Identify input factors which represent experimental "noise".
4. Determine the range for each variable input factor.

### *Select Variable Input Factors*

To determine which input factors to include as variable input factors in the DoE, examine existing laser welding production processes. For this example, the following variable input factors were selected:

1. Peak power
2. Pulse duration or pulse width
3. % Weld spot overlap
4. Weld spot location in relation to the weld junction

### *Select Fixed Input Factors*

Next select what input factors to fix or hold constant. Note that Tip/Shaft Assembly rotational speed and the frequency or pulse repetition rate control the % weld spot overlap. The easiest parameter to vary is the pulse repetition frequency. Therefore, fix the Tip/Shaft Assembly rotational speed. The table in Figure-5 represents the fixed input factors.

| Parameter | Value |
|---|---|
| Mode | Single Pulse |
| Pulse Shape | Square |
| Weld Spot Diameter | 0.46 to 0.50-mm |
| Spot Focal Point | Part Surface |
| Rotational Speed | 9.0-RPM |
| Laser Beam Angle | Perpendicular to Part Surface |
| Cover Gas | Argon |
| Cover Gas Flow | 30 to 35 CFH |
| Cover Gas Nozzle | Part of Focusing Head |

Figure 5 – Fixed Input Factors

### *Noise Factor Identification*

Uncontrolled input factors, which represent experimental "noise", include variations in the weld junction gap and the weld spot location in relation to the weld junction. The measured limits of both noise sources are listed in the OQ section.

### *Variable Input Factor Range*

The experimenter must know which variable input factors are important in producing the desired output responses. A common misconception regarding DoE's is that the DoE should produce only perfect welds. A DoE study that produces only perfect welds does not tell the experimenter how the variable input factors affect the output responses.

Therefore, the experimenter must conduct a series of trial and error "mini" experiments to determine the range for each variable input factor that produces both "cold" and "hot" welds. Visibly, "cold" laser welds produce voids or incomplete weld flow around the Shaft circumference, and "hot" laser welds produce unacceptable weld splash and distortions in the weld flow around the Shaft circumference. Using these definitions for "cold" and "hot" laser welds resulted in the following variable input factor ranges for the surgical tool example shown in Figure-2. See the table in Figure-6. Note that Overlap is really one variable where the pulse repetition frequency (Hz) controls the Overlap %.

| Parameter | Cold | Nominal | Hot |
|---|---|---|---|
| Power (watts) | 106 | 113 | 120 |
| Pulse Duration (ms) | 6.0 | 7.0 | 8.0 |
| Location (mm) | -0.15 | 0.00 | +0.15 |
| Overlap (%) | 80 | 85 | 90 |
| Overlap (Hz) | 11 | 16 | 21 |

Figure 6 – Variable Input Factor Range

***Conduct the DoE***

A D-Optimal model with 4-variable input factors, 6-replicates, and 3-output responses was used. The D-Optimal model provides 2-order interactions with excellent model strength and requires less parts compared to using a full factorial model. The 3-ouput responses included: a) burst pressure, b) weld width and c) void length.

Figure-7 presents the ANOVA Table for the 3-output responses. The burst pressure and weld width model results are very strong, with Error values of 13.77% and 11.21% respectively. Weld spot location is the primary input factor affecting the burst pressure while pulse duration in the primary input factor affecting the weld width. With an Error value of 84.56%, the void length model is meaningless. Correlation studies showed no correlation between the weld width and the burst pressure. Therefore, weld width and void length can't be used as non-destructive PQ weld quality metrics.

| Source | Burst Pressure % Contribution | Weld Width % Contribution | Void Length % Contribution |
|---|---|---|---|
| Power (A) | 12.31% | 20.16% | 7.32% |
| Pulse (B) | 6.17% | 44.81% | 3.00% |
| Location (C) | 53.95% | 2.92% | 3.97% |
| Overlap (D) | 13.81% | 20.90% | 1.15% |
| Error | 13.77% | 11.21% | 84.56% |

Figure 7 – DoE ANOVA Results

***Optimize the Welding Parameters***

The surgical tool shown in Figure-2 is typically pressurized during Product Performance Qualification (PPQ) to 20.68-MPa (3.0-ksi). The product design team specified an optimized target goal of 96.53-MPa (14-ksi) and no voids. The Marginal Means graph for burst pressure shows that achieving the optimized value is possible. See Figure-8.

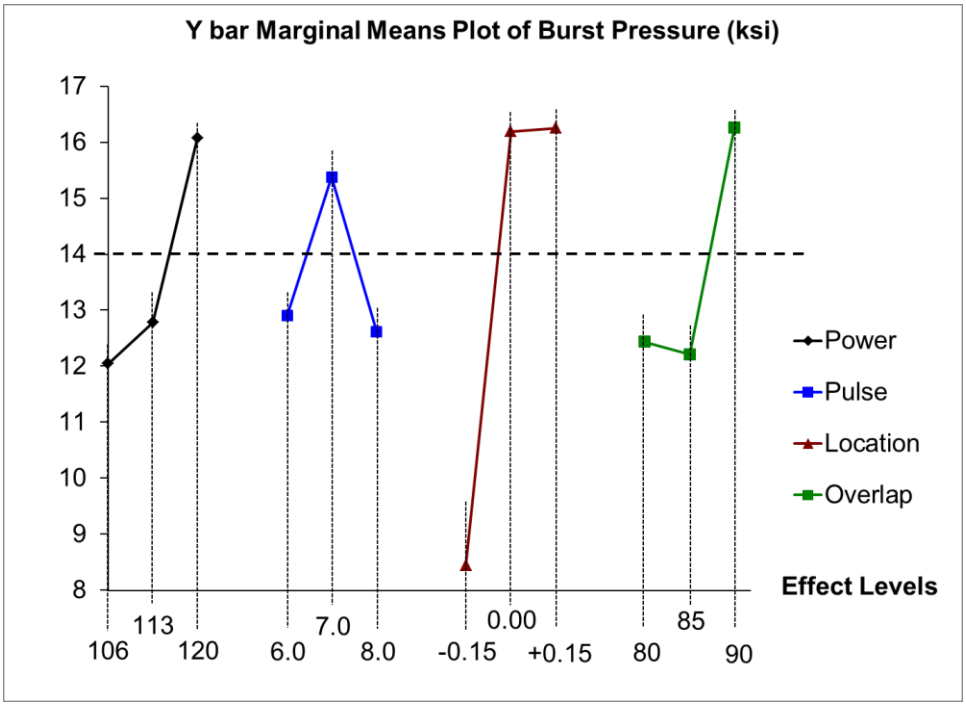


Figure 8 – Marginal Means Graph for Burst Pressure

Using DoE expert prediction software produces the following optimized set of laser welding parameters for the surgical tool. See Figure-9.

| Parameter | Nominal | Allowable Range |
|---|---|---|
| Power (watts) | 117 | +3, -2 |
| Pulse Duration (ms) | 7.0 | ±0.1 |
| Location (mm) | 0.00 | ±0.015 |
| Overlap (°) | 90 | ±1.0 |
| Overlap (Hz) | 21 | ±0.0 |

Figure 9 – Optimized Laser Welding Parameters

### *Determine the Lot Run and Sample Size*

Recall that the most significant input factor controlling the burst pressure is the location of the weld flow pattern (width) from the weld junction. Therefore, the PQ acceptance metric will use the weld spot location deviation for qualifying the laser welding process. To prepare for the PQ Confirmation Run, determine the Lot Run and Sample Size. Use Statistical software such as Minitab® to calculate the sample size and acceptance criteria. The acceptance testing can use Z-Test statistics or a minimum Cpk value. The acceptance criteria for a Z-Test is called the "K-value".

### *Confirmation Run Sample Size and K-Value Calculate*[6,7,8,9]

1. Data is variable data.
2. Production lot run size is normally 2,000 pieces.
3. AQL is 0.023% (5-Sigma = Cpk=1.67).
4. RQL is 0.15% (5-Sigma = Cpk=1.67).
5. Lower limit based on the maximum deviation of the weld flow pattern from the nominal weld junction that will absolutely prevent weld voids is -0.10-mm.
6. Upper limit based on the maximum deviation of the weld flow pattern from the nominal weld junction that will absolutely prevent weld voids is +0.10-mm.
7. Historical standard deviation, as estimated from optical measurements of the maximum range of the weld flow pattern from the nominal weld junction is 0.015-mm.
8. Using 1 through 7, Minitab-15® calculates a minimum sample size of (30) welded pieces for each operator and an acceptance K-value of 3.2.

### *Conduct the Confirmation Run*

Use three operators to make 30-samples each, for a total of 90-samples using the test conditions defined in Figure-10 and the fixed parameters listed in Figure-5. The Confirmation Run is conducted at two different power levels to test the use of a wide weld window during production. Note: "X" represents the operator identification code.

| Weld Number | Laser Power (W) | Pulse Duration (ms) | Overlap (%) | Weld Spot Location (mm) |
|---|---|---|---|---|
| X-01 to X-15 | 115 | 7.0 | 90 | 0.00 |
| X-16 to X-30 | 120 | 7.0 | 90 | 0.00 |

Figure 10 – PQ Challenge Laser Welding Parameters

Before removing each laser welded sample from the laser welding system, measure and record the weld spot location deviation from the weld junction using the following measurements as shown in Figure-11.

1. Measure and record D1.
2. Measure and record D2.
3. Calculate and record Weld Width, D3 = D1 + D2 (ignore the minus sign on D2).
4. Calculate and record Weld Location Error, D4 = D1 – (D3/2).
5. Use D4 for determining PQ acceptance or rejection.

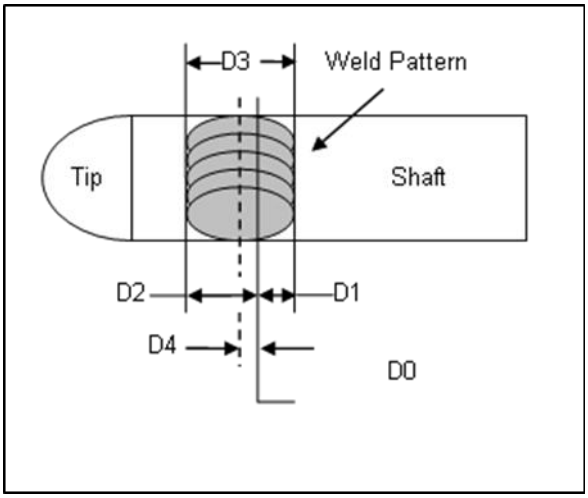

Figure 11 – Weld Location Measurement

6. After measuring the weld spot location for each sample, submit the samples for Process Validation (PV) testing.

***Apply the PQ Acceptance Criteria***

Calculate the average and standard deviation of the weld spot location using the 30-sample PQ data from each operator. Next, calculate the Z-Test statistics, Z.LSL and Z.USL for each operator using the following formulas:

1. Z.LSL = [(Average weld location error) + (0.10-mm)] / Standard Deviation
2. Z.USL = [(0.10-mm) – (Average weld location error)] / Standard Deviation

The table in Figure-12 shows the Calculated Z.LSL and Calculated Z.USL for each operator.

| Welding Operator | Calculated Z.LSL | Min Z.LSL Value | Z.LSL Pass/No Pass | Calculated Z.USL | Min Z.USL Value | Z.USL Pass/No Pass |
|---|---|---|---|---|---|---|
| A | 10.50 | 3.2 | Pass | 10.46 | 3.2 | Pass |
| B | 17.47 | 3.2 | Pass | 16.90 | 3.2 | Pass |
| C | 12.50 | 3.2 | Pass | 11.32 | 3.2 | Pass |

Figure 112 – Z-Test Results, PQ Confirmation Run

All three operators successfully laser welded Tip/Shaft Assemblies that passed the PQ acceptance criteria for the weld spot location and contained no voids. The worst case weld spot location error across all three operators was ±0.025-mm. This value is four times less than the upper/lower limit range of ±0.10-mm. Thus, the laser welding process is "qualified", but still requires process validation testing.

## Process Validation (PV)

Process Validation (PV) establishes that the welding process consistently produces a part or product meeting its predetermined specification. PV metrics must represent the stresses encountered during product usage. PV metrics must also be different from the PQ metrics. Process validation involves correlating the PQ data with the PV data.

For the surgical tool example shown in Figure-2, the first PV weld quality metric is a leak test using helium gas. The entire surgical tool must not leak at a test pressure of 6.89-MPa (1.0-ksi) over a 20-second test period. There can be no helium gas bubbles surrounding or emanating from the laser weld.

The second PV weld quality metric is an outer diameter (OD) test across the entire surgical tool shaft length. The OD must range between 2.36 to 2.45-mm in order to fit into a guiding tool and not be too loose. A laser weld does not have a flat surface. The OD across the laser spot weld width can vary, depending on the laser power and duration. All 90 PQ Confirmation samples submitted for PV testing passed both PV weld quality tests.

21 CFR Part 820.75 (b)(2) simply states that monitoring and control methods must be determined[10]. To ensure that weld spot location is properly controlled, the worst case weld spot location deviation from the weld junction measurement obtained within a single lot must be recorded on the lot traveler. The limit for the weld spot location from the weld junction is ±0.095-mm in order to ensure that the actual Z.LSL and Z.USL values remain above the critical K-value of 3.2.

## Product Performance Qualification (PPQ)

**PPQ** establishes with documented evidence that the finished product meets all requirements for functionality and safety. PPQ incorporates a series of environmental tests used to simulate the operating environment of the finished product. PPQ environmental tests include, but are not limited to: life cycling, temperature, vibration, humidity, impact, and shipping. Assuming that no failures of any type occur, the product is considered to be validated. Should weld failures occur during PPQ, the basic product design for weldability must be re-visited and the laser weld re-validated.

The surgical environment is well controlled in terms of temperature and humidity. The only impact and vibration stresses come from the shipping process, which must pass the appropriate DOT specifications.

For the surgical tool example shown in Figure-2, the first PPQ product metric is a pressure test using argon gas. The entire surgical tool must not leak at an operating pressure of 20.68-MPa (3.0-ksi) during the duration of the surgery. There can be no argon gas escaping from any part of the entire surgical tool assembly.

The second PPQ product metric is a tip temperature test. The tip temperature must remain at -80°C or lower during the surgical procedure. All 90 PQ Confirmation samples submitted for PPQ testing passed both PPQ product tests.

## Conclusion

Laser welding validation is no longer limited to the realm of medical device or automotive sensor manufacturing. Validation is a proven systematic method to improve process and product quality, reduce product scrap and field failures, and enhance the competitiveness of your product. Six-sigma oriented manufacturers are quickly discovering the economic benefits of establishing and maintaining validation over their laser welding processes.

## About the Authors

David Steinmeier is a manufacturing process expert in the field of packaging and assembling miniature and micro-miniature electronic and electro-mechanical products for the aerospace, automotive sensor, commercial electronics and electro-mechanical, and medical device industries. He has extensive experience in developing, optimizing, and validating laser and resistance welding processes. David can be reached at: david@microjoining.com.

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10. 21 CFR Part 820.75(b)(2) "Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met."