DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 14(18), 2741-2748 (1988)

EXPANSION WITHOUT SHUTDOWN OF AN OPERATIONAL PHARMACEUTICAL PLANT USING AUTOMATIC ORBITAL TIG WELDING TECHNIQUES

by

Barbara K. Henon, Ph.D.
Arc Machines, Inc.
Pacoima, California

Introduction

In 1986 a pharmaceutical plant in Puerto Rico was faced with the need to expand their facility in order to convert from the manufacture of capsules to caplets. The expansion was needed in order to increase the capacity of the facility to meet the large demand for this product. The pharmaceutical company, which was faced with the loss of potential sales, put the mechanical contractor, Standard Refrigeration, under pressure to complete the project as quickly as possible. The expansion involved the installation of a piping system from an existing facility, through a warehouse, into Phase II, a new wing which was under construction. The piping included both a high-purity DI water system, and non-critical carbon steel piping.

A significant part of the project was the installation of an 8 inch diameter schedule 40 carbon steel pipeline for chilled water, and a 6" carbon steel steam line and condensate return. The piping had to be installed through the warehouse which was filled with cardboard boxes and other flammables.

Piping is used extensively throughout the pharmaceutical industy and is fundamental to the operation of most (if not all) pharmaceutical plants. The quality of a piping system will depend not only upon the quality of the materials used, but will also depend to a great extent upon the quality of the techniques used for joining the system. Manual TIG (tungsten inert gas) welding has been used for many years for joining stainless steel pharmaceutical tubing, replacing the use of compression fittings which tended to leak and lead to corrosion of the sytem. In recent years we have seen a marked increase in the specification of automatic orbital TIG welding for high-purity pharmaceutical and biotechnology applications.

Although automatic orbital TIG welding was specified for the DI water system, the unique aspect of this installation was the specification of automatic orbital pipe welding for the non-critical carbon steel pipeline. Orbital pipe welding equipment is commonly used in the nuclear industry and in other code critical applications, but as far as we know, this was the first pharmaceutical application of this type of equipment.

Factors Involved in Choice of Welding Procedures

Once welding has been selected as a joining process, the most appropriate welding process for the job would have to be determined. The decision on a particular welding process would be based on several factors:

Application: A choice of procedures would require an evaluation of the application: what level of quality is required for this application? What material is to be used? Does the weld have to meet X-ray inspection, will the pipe be subjected to high pressure or temperature, or will it be exposed to corrosive material? What level of purity is required, and how will this standard be maintained once the system is in operation? Clearly, the quality requirements for the high-purity stainless DI system would be very different from those of the carbon steel steam and chilled water lines.

Economic Factors: These would include such considerations as the cost of equipment, the cost of materials, the the skill level and thus cost of personnel required, and the relative speed of the possible processes. Also included would be the major consideration of whether the installation could be completed without the necessity for shutting down production. A nominally more costly and slower welding process might be more cost effective than a faster, cheaper welding process if it could be implemented without the need of shutting down production.

Special Considerations: These are conditions specific to a particular job or situation. For the carbon steel piping, the location posed a special problem. This was the requirement that the piping should be installed 28.5' above the floor in a warehouse filled with flammable material. The welding process selected for this application would have to present a minimum risk of fire and be sufficiently clean that it would not affect the operating environment of the pharmaceutical manufacturing process.

Comparison of Welding Processes

Shielded Metal Arc Welding: The SMAW process, (commonly referred to as stick welding), would typically have been selected for the carbon steel piping system. SMAW is a simple and versatile process which uses a covered electrode consisting of a core wire surrounded by a baked-on, clay-like covering. The covering is a source of arc stabilizers and gases which serve to displace the atmosphere, and metal slag which protects and insulates the hot metal and prevents its oxidation. The uncovered end of the electode is clamped in an electrode holder which is connected by a cable to a welding power supply. The welder initiates an arc by touching the electrode to the metal and then slightly withdrawing it. The base metal, as well as the wire core of the electrode and metal powders in the covering, contribute to the finished weld.

This process, particulary for all position welding, such as a circumfrential weld around a pipe, requires a very high degree of welder skill. Both the quality and the speed of the welding are highly dependent upon welding skill. Furthermore, slag material must be removed between each pass which contributes to the overall time and labor costs. One clear advantage of the process is that the equipment is relatively cheap with costs in the range of \$500-1500 for a typical production package. Material costs are fairly high since only about 60% of the electrode material is deposited as filler metal.[1]

Because of the fumes and smoke produced by this process, as well as the fire hazard created by falling sparks, the use of the stick welding process would have required evacuation of the warehouse and shutting down production of the entire plant.

Manual TIG (GTAW) Welding: Gas tungsten arc welding uses a nonconsumable tungsten electrode which must be shielded with an inert gas. The gas shield protects the electrode and molten weld puddle from oxidation and contributes to the arc characteristics. Equipment needed consists of a welding torch, a welding power supply, and a source of inert gas with suitable regulators and flowmeters. As with stick welding, a face shield and protective clothing are required. A constant current, usually DC, power supply is required which may incorporate a high-frequency arc start circuit to intiate an arc without the necessity for touch start. The high frequency arc start contributes to the overall quality of the process by eliminating tungsten inclusions in the welds.

A small manual TIG welding setup will cost in the range of \$1,000. The equipment can be portable, and suitable for a wide range of materials and applications. The cost of the inert gas makes it a more expensive process than SMAW, but there is no need for grinding between passes. Manual TIG welding requires more training time, manual dexterity and welder coordination than stick welding, but it can be done in all positions. Although the highest quality welds can be achieved with this process, weld quality is totally dependent upon the skill of the welder. Manual TIG welding may be done as a fusion weld without the use of filler wire on thin-walled materials of close dimensional tolerances, such as most standard pharmaceutical tubing with a wall thickness of 0.065". Heavier, less regular material which includes most pipe sizes having a wall thickness in excess of 0.134", would usually require the use of filler wire which is fed into the weld puddle and incorporated into the weld. When filler wire is used with manual welding, the amount of heat required to make the weld can result in carbide precipitation. This condition occurs when excessive heat is applied to the metal causing carbon to precipitate out of the material matrix and combine with chromium in the steel to form chromium carbide. When this occurs, the base metal in the grain boundaries is depleted of chromiuim and is highly susceptible to rust and corrosion.

<u>Automatic Orbital TIG (GTAW) Welding:</u> Automatic orbital TIG welding incorporates the TIG process as described above into equipment in which the weld parameters are controlled by the power supply and the entire weld is completed automatically without further operator intervention following initiation of the weld sequence by pushing a button. This equipment can be divided into orbital tube welding equipment for doing fusion welds on tubing and small diameter pipe, and the more complex pipe welding equipment, which is used on larger diameter heavier walled piping, and is capable of adding filler wire into the molten weld puddle.

<u>Orbital Tube Welding</u>: Automatic orbital tube welding equipment for fusion welding generally includes a portable solid-state DC power supply, associated cables, and an enclosed weld head containing an internal rotor which holds a tungsten electrode, and which rotates around the work to do the weld. The tube or pipe, therefore, remains in place, which allows the weld head to be placed in close proximity to a wall, a ceiling, or between closely spaced lines of tubing or pipe. Precise rotational control is provided by a motor and tachometer feedback servo loop. Compact, portable tube welder power supplies which plug into 115 VAC and provide total control of the welding sequence, and which are rugged enough to stand up well to construction site conditions, are ideally suited for pharmaceutical applications.

To make a weld, the welding operator dials a program into the power supply control panel, installs the tubing in the weld head, and pushes a button to start the weld sequence. There are minor differences among the manufacturers, but all of the welding parameters from a timed pre-purge, during which the weld head is filled with inert argon gas, through postpurge, which continues the argon purge to prevent oxidation after the weld is completed, are controlled by the power supply without operator intervention.

Arc strike is initiated automatically, and pulsation, rotation delay, timed levels of current control which modulate the heat input as the tungsten travels around the weld joint, and a downslope which gradually tapers off the welding current are all handled by the power supply. The accuracy of these controls is within ± 1% of the dial settings, and pulsation is used to reduce the heat input into the material and to control the weld puddle. Essentially, the fusion weld consists of a series of spot welds in which the main welding current penetrates the material and the background current chills the puddle. The accuracy of the power supply and the additional control provided by pulsation makes possible a level of control and repeatability that is unattainable with manual techniques. This precise control of the heat of welding virtually eliminates the possibility of carbide precipitation. In addition, the weld program provides complete documentation of the weld parameters which would not be possible with manual welding techniques.

Automatic orbital tube welding equipment is considerably more expensive than either stick or manual TIG equipment with a basic system of a power supply and one weld head selling for about $20,000. In addition, the quality of automatic welds depends upon the quality of weld joint preparation to a much greater extent than does manual welding. The tubes must be squarely cut in order to meet properly in the weld head, and the ends must be machined to a square butt joint configuration without burrs or chamfer. While the operator of automatic orbital tube welding equipment need not be a skilled manual TIG welder, it is important that he be fully trained on the equipment, since the quality of the weld still depends on factors controlled by the operator as well as those controlled by the equipment.

Although the arc time for an automatic fusion TIG weld is usually less than that of a comparable manual TIG weld, the actual speed of a job done with automatic equipment will depend on a variety of factors. The highest efficiency is obtained when there are a large number of welds of the same size to be welded consecutively. The increase in preparation time for automatic orbital TIG welding relative to manual TIG welding can usually be offset by the considerable savings in time which can be realized by eliminating the necessity for rework.

Automatic Orbital Pipe Welding: Orbital Pipe Welding would be used for welds requiring filler material such as heavy walled pipe-to-pipe welds. Power supplies for orbital pipe welding are considerably more complex than those used for fusion tube welding. Additional controls for feeding wire, for oscillation of the torch to weave the weld bead across the joint and to allow for cross seam adjustment during welding, and AVC (arc voltage control) to maintain a constant arc gap over uneven surfaces are standard for this type of welding equipment.

Automatic Orbital Pipe Welding equipment, particularly that at the higher end of the cost range is expensive, about $40-50,000 for a basic system. Although a saving in time relative to manual SMAW pipe welding is possible, it would depend on any number of factors. The time savings, if any, would be most favorable on pipe sizes greater than 6 inch. However, automatic TIG welding is about 4-5 times faster than manual TIG welding[2], so considerable time savings are possible for applications where the TIG process is required. The process is highly repeatable with only ± 1% variation in power supply controls so that rework time is held to a minimum.

The Carbon Steel Pipeline

The piping for chilled water, steam, and condensate return, used for cleaning of the high-purity DI water system, were not required to be of the same high quality as the DI water system which would have direct contact with the product. This was a non-critical system which would not be subject to pressures above 50 psi or to hazardous materials. Carbon steel was selected for this application rather than the more costly stainless steel, and the welds were not required to be of X-ray quality. The usual welding procedure for this type of application, essentially just a seal weld, would have been SMAW. However, the fumes and smoke produced by the SMAW welding process would have been totally unacceptable in a working pharmaceutical plant.

Although measurable amounts of fumes are given off during TIG welding, they would be insignificant in comparison to stick welding, and TIG welding would present a negligible risk of fire. In order to avoid shutting down the facility during the expansion, which would have further delayed the conversion to the production of the caplets, the only acceptable processes for welding the carbon steel piping were manual TIG and automatic orbital TIG. Even considering the higher cost of equipment, the owners specified the use of automatic orbital pipe welding for the carbon steel piping for the speed advatage compared to manual TIG.

The equipment selected to weld the 8 inch carbon steel chilled water line and the 6 inch carbon steel steam and condensate return line consisted of an AMI model 105 orbital pipe welding power supply and an AMI model 15 weld head with wire feed. Although no sparks are given off by the TIG process, special precautions such as using a short tungsten were taken to fully shield the arc in order to eliminate any potential fire hazard while the piping was being welded 28' 6" above the warehouse floor. The actual welding times, including set up, for the 6 inch pipe and the 8 inch pipe were comparable to published figures for SMAW of about 1 hr 15 min to weld a 6 inch pipe and 1 hr 51 min. to weld an 8 inch pipe[2].

High Purity Piping System

The FDA has recently become more vigilant in their acceptance of high- purity piping systems carrying water for pharmaceutical use, since they have found that 65% of product recalls due to microbial contamination could be traced to water systems not validated for purity[3]. The necessity of maintaining a high degree of product purity is common to the pharmaceutical and electronics industries. Over the past few years, the concept of a high purity piping system to prevent chemical, particulate or bacterial contamination of ultra-high-purity liquids or gases has undergone considerable evolution. A high-purity piping system is one that is designed and built to meet certain analytical criteria. In the electronics industry the primary contaminants are particulates and chemical, while bacterial contamination is of particular concern in pharmaceutical applications because of the danger of product contamination and possible threat to human health[4].

A systems approach to meet the specified criteria would define the materials and methods of construction as well as the system design, and would also specify the criteria for validation and acceptance of the system by the owner after completion of the system[5,6]. The requirements for the high-purity stainless steel DI water system in the Puerto Rico installation were determined by the necessity for highly purified distilled water. The purified water is mixed with the protein coating used to facilitate swallowing of the caplets. Water to be used in non-sterile pharmaceutical products such as this demands a piping system with a very smooth ID surface, free of rough spots or scratches where bacteria could colonize and contaminate the system. In addition, DI water is a highly corrosive environment for stainless steel, so it is very important that the welding procedure used not compromise the metallurical properties of the tubing that might cause the metal to lose its resistance to corrosion.

Because of the quality requirements of the system, and because of the economic pressure to complete the installation within a highly compressed period of time, the automatic orbital TIG welding process was specified for the high-purity stainless steel DI water system.

Installation of the DI Water System

The DI water piping system constructed by Standard Refrigeration was designed and installed in such a way as to make it possible to maintain the required high levels of purity,and where cleaning of the system could be accomplished easily and effectively.

The high-purity DI water system forms a continuous loop from a storage tank outside the building to the solution prep tanks, where the protein coating solution is prepared before it is sprayed on the caplets, back to the storage tank. The material chosen for the piping system was 316L stainless steel, an alloy that is relatively inert and which has good resistance to corrosion. Water is carried from the storage tank to the solution prep tanks via 2 inch OD 0.065" wall tubing, and unused water is returned to the storage tank via 1-1/2 inch OD tubing. The prepared solution is transferred from the solution prep tanks to the coating machines where the coating is applied to the caplets. Six coating machines are planned for the completed installation.

Water is heated to 180° F from the supply temperature of 90°F after leaving the storage tank, and pumped through the new building, called Phase II, to the solution prep tanks. Some of the water is diverted for cleaning purposes and is used for sterilization of the tanks, and cleaning and washing of the coating pans. The valves for this system were automatically welded to 3/4 inch OD lines and they open automatically to clean the coating pan. The coating pan is then flushed with purified compressed air so that no water stays in the pan.

Design Consistent with FDA Good Manufacturing Practices

The system design is consistent with the FDA design criteria for Large Volume Parenteral Good Manufacturing Practices (LVP-GMPs) intended to minimize bacterial colonization and growth in a sanitary piping system[6]. The continous loop design of the DI water system allows for constant motion of the water in order to prevent bacteria from settling to a surface where a colony could form. The surface area of the ID of the the tubing was held to an absolute minimum by polishing to a 180 grit mill finish. The smooth weld bead made possible with automatic welding techniques assured a continuous smooth ID surface and eliminated sites where bacteria could settle and grow.

This system was designed and constructed to eliminate dead legs at the points of use in accordance with the FDA LVP-GMPs which say that no section of piping longer than 6 times its diameter should exist without continuous flow. In addition, the piping system was sloped at a 1°

angle (1/8 inch per foot) to allow for complete drainage of the system during cleaning. Expansion loops were designed into the system to allow for expansion of the heated stainless steel tubing.

Construction Techniques

The construction techniques were also designed to insure the cleanliness and purity of the finished piping system. Most of the welding was done in a separate fab shop maintained exclusively for stainless steel tubing. Sections of the piping system were preassembled and welded in the shop, and then capped and bagged in plastic for later installation in the field. This kept the number of field welds to a minimum, reducing the risk of system contamination. Each of the 712 welds was numbered and the number recorded in a daily welding log and engraved on the tubing next to the weld.

Tubing sizes from 3/4 inch to 2 inch O.D. were welded in the same weld head by changing the tube clamp inserts which hold the tubing in the weld head. A portable tube facing lathe made by Tri-Tool, Rancho Cordova, California, was used for squaring the ends of the tubing prior to welding. One of the two weld heads was used in the standard configuration while the second head was converted to the "E" configuration in which the tungsten is located at the edge of the rotor while the clamp housing is removed on one side of the head. This made it possible to weld pharmaceutical type fittings such as elbows, tees, or ferrules with a short (approximately 1/4") straight section to a tube.

Although welds done in an "E" type head require tacking prior to welding, most of fittings used on this job were made by Ladish-Triclover and had a long straight section suitable for welding in a standard weld head without pretacking. When pretacking was required, this was done with a manual TIG torch connected to the portable tube welder power supply. It should be mentioned, that for a high-purity application, it is absolutely essential to purge the ID of the tubing during tacking. This is true, even if the tack does not penetrate to the ID of the tubing. Oxidation can form in the crevice between the tubes which may deflect the arc, leaving a site where bacteria can grow and corrosion begin.

Weld Parameters

Standard pharmaceutical grade stainless steel tubing with a wall thickness of 0.065 inches is commonly welded with about 65-75 Amps of primary welding current at a tungsten electrode travel speed along the tube surface of around 5 inches per minute. However, Standard Refrigeration elected to use the Synchro function of the 107 power supply which synchronizes the weld head rotation with the current pulses. This technique, in which the rotor is stopped during the high current pulses and advanced during the low current pulses, provides greater penetration and weld puddle control than equivalent currents applied during continuous rotation.

Although Synchro welding is slower, Project Manager and Standard Refrigeration owner, Bill Wood, felt that weld quality was increased, particularly when welding different heats of material together or when welding fittings or valves to tubing. In Synchro, the arc time for a 2 inch OD weld was 2 minutes, 2.9 seconds. They were able to realize a high degree of productivity and achieved a maximum of 68 welds on one day using two welding systems.

QC and System Validation

Although manual welding skills are not required to operate an automatic orbital tube welding system, a good knowledge of the welding process and the ability to discriminate between good and bad results are required. Operator training should be a required part of the welding QC program for any high-purity piping application. Welders are generally required to make a test coupon each morning using an approved weld schedule for a particular size of tubing. If the test weld is good, the chances are excellent that subsequent welds done under the same conditions will be identical. An important part of welding QC is visual examination of the outside of the finished weld, but weld defects such as lack of penetration, poor or no ID purge, or excessive I.D. purge pressure, can only be determined by examination of the ID of the weld. Incomplete penetration of some portion of the weld joint would leave a crevice on the ID. Although the probability of a leak would be very low, such a crevice would provide a site for bacteria to become established, where contaminants could become entrapped, and where corrosion could begin.

In order to verify weld quality, Standard Refrigeration used a Welch Allyn Video probe 2000 electronic borescope to visually inspect the ID of each weld as it was completed. A 20 foot flexible fiber optic probe (Video Endoscope) was inserted into the tube ID and the weld joint was projected in clear detail on a Panasonic Color Video Medical Monitor. Any welding defects, such as a poor I.D. purge or incomplete fusion, would have been displayed in full color. Although a color image has less resolution than black and white, it provides more information concerning the details of the weld. A problem detected by this method could have been corrected easily at this stage of construction but would have been consderably more difficult as well as expensive to repair after the entire system had been installed.

System Validation

The FDA inspector was permitted to break the insulation around the completed portion of the piping system in order to inspect a weld, and if the weld was defective, the contractor was expected to repair it at his cost. The use of automatic tube welding equipment held such replacement costs to an absolute minimum. The closed loop DI water system was completed with no major flaws, and then subjected to further testing. First it was filled with tap water and tested for hydronic leaks, then the system was filled with steam at the required temperature and tested again for leaks. Following the leak test, the system was passivated with NaOH, neutralized with nitric acid, and flushed with DI water which was allowed to circulate through the system for two days. The system was flushed two more times with DI water, and a sample of the water from the third batch sent to the lab for testing. The sample was found to meet all the required tests for bacteria, minerals, and organic compounds, completing all requirements for validation of the system.

Summary

Standard Refrigeration was on site in April, 1986 and was given a rather ambitious time schedule of approximately seven months to complete the entire installation, including the piping. After the project was begun, the owners moved the completion date ahead by one month and applied pressure to the contractor to meet the new deadline. The owners had hoped to have one coating machine for the caplets up and running by Sept. 1, 1986. While the scope of the work was effectively tripled, the time frame was reduced. The contractor did not get engineering drawings for the piping system until July. Personnel training on the tube welding and pipe welding equipment was done during the first week of August, and the first production weld was done on August 16. The first real production run in which actual coating of the caplets occurred was accomplished by November 13, 1986. Thus, the actual construction of the system was completed in about three months, making this the fastest sanitary project that Standard Refrigeration had ever been involved with.

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