

Business Profile



FORT WAYNE METALS

Turning knowledge into solutions.®

Business Profile

Summary

Fort Wayne Metals has developed a Quality Management System (QMS) to better satisfy the needs of its customers, to involve all employees, and to improve the management of the company. It consists of the quality manual, procedures, work instructions, and forms. The QMS continues to develop to comply with applicable statutory and regulatory requirements, our customer's expectations, and our objectives.

FWM has been registered with the FDA as a contract manufacturer since 1976. Although none of our activities are considered contract manufacturing by the FDA, our customers find value in our continued registration with the FDA and compliance with 21 CFR Part 820. We produce components as defined in FDA 21 CFR Part 820.3 under what ISO considers a contract manufacturer. None of the products produced meet the definition of a medical device as defined in ISO 13485 section 3.7. Fort Wayne Metals does not sterilize, package for use, or label for use medical devices.

The purpose of the Quality Manual is to document Fort Wayne Metals' quality system, to instruct and guide employees whose actions affect product quality, and to inform the company's customers what controls are implemented to assure product quality. The Quality Manual serves as an official reference in understanding and applying the quality policies and philosophies of the company.



1.0 Business, Administrative, and Contact Information

- 1.1 Fort Wayne Metals Research Products Corp.
- 1.2 Privately Held, Non-union Company,
Large Corporation.
- 1.3 D&B # 05-604-1122
SIC Code - 3315
NAICS - 331222
- 1.4 Tax ID # 35-118-6549

2.0 Contact Information

- 2.1 PHONE 260.747.4154
- 2.2 FAX 260.747.0398
- 2.3 **Mark Michael** PRESIDENT & COO
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- 2.4 www.fwmetals.com
- 2.5 9609 Ardmore Ave.
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- 2.6 P.O. Box 9040
Fort Wayne, IN 46899



3.0 Business Introduction

3.1 Fort Wayne Metals (FWM) was founded in 1970 to produce medical grade wire. Today's products include round wire, shaped wire, strands, cables, bars, coated products, and assemblies of over one hundred different alloys. The majority of the products produced are utilized in the medical device industry with the balance being utilized in aerospace and industrial applications.

The company's headquarters is located in Fort Wayne, Indiana with manufacturing facilities in Fort Wayne, Indiana, Columbia City, Indiana, and Castlebar, Ireland. The raw material requirements of the Castlebar facility are supplied by the Fort Wayne, Indiana facilities. Commercial products are shipped from each manufacturing location. Additional company information can be found at www.fwmetals.com.

3.2 Manufacture and distribution of bars, specialty fine wire, cables and assemblies for aerospace & defense, industrial, medical devices and other applications.

3.3 Certifications

AS9100C & ISO9001 -74 300 3389
Exp. date-February 7, 2017-TUV Rheinland of North America Inc.

ISO 13485 for ABG only (9823 Ardmore Ave) - SX 60038936 0001 Exp. date Aug 6, 2016 - TUV Rheinland of North America Inc.
ISO 17025 -2577.01 & 2577.02
Exp. date Sept 30, 2015 - A2LA

FDA Registered 1824313 - Last FDA Audit 1996 no 483 or warning letters

3.3.1 Exclusions from Industry Standards

ISO 9001, AS/ISO 9100, ISO 13485:

SECTION 7.3 - DESIGN AND/OR DEVELOPMENT

Fort Wayne Metals manufactures components to the customer's designs and specifications. While we may provide recommendations related to Design-for-Manufacturing, tolerances, or materials, the customer is responsible for product design requirements and the approval of any Fort Wayne Metals provided recommendations.

AS/ISO 9100:

SECTION 7.5.1.4

Fort Wayne Metals does not service parts after shipment. Components are manufactured and delivered to customers. Customers use the components to produce parts and assume service ownership of the parts produced.



3.3.2 Non-Applicability

The following sections of ISO 13485 have been omitted from the quality management system because the product realization requirements are not applicable due to the nature of the products provided by Fort Wayne Metals.

SECTION 7.5.1.2.2 - INSTALLATION ACTIVITIES

Fort Wayne Metals does not install or verify installation of medical devices.

SECTION 7.5.1.2.3 - SERVICING ACTIVITIES

Fort Wayne Metals does not service medical devices.

SECTION 7.5.1.3 PARTICULAR REQUIREMENTS FOR STERILE MEDICAL DEVICES

Fort Wayne Metals does not sterilize medical devices.

SECTION 7.5.2.2 PARTICULAR REQUIREMENTS FOR STERILE MEDICAL DEVICES

Fort Wayne Metals does not produce or sterilize products.

SECTION 8.2.4.2 PARTICULAR REQUIREMENTS FOR ACTIVE IMPLANTABLE DEVICES AND IMPLANTABLE DEVICES

Fort Wayne Metals does not produce medical devices.

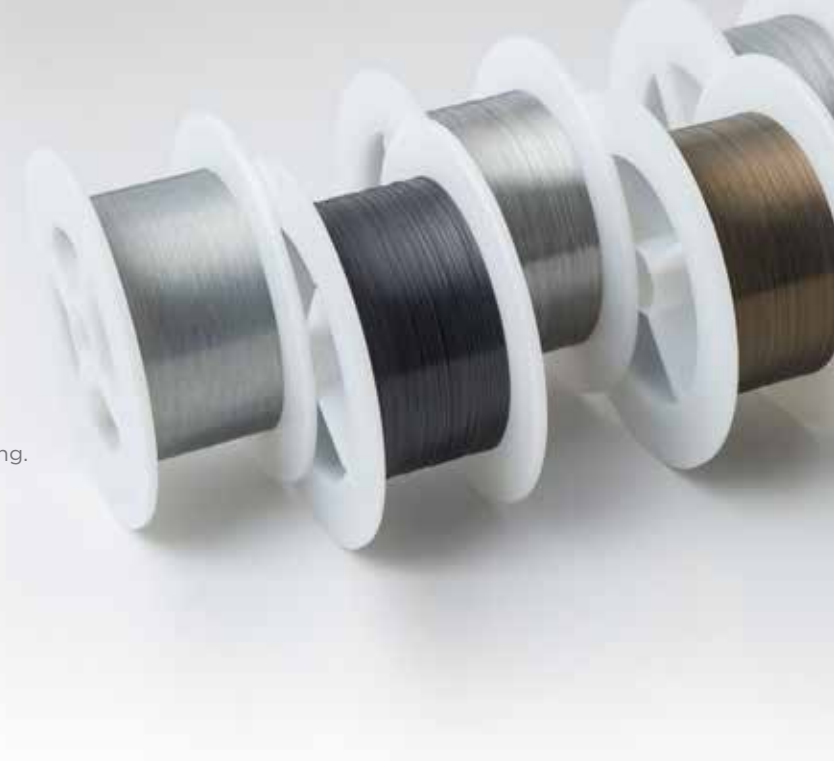
4.0 Business Strategy

4.1 Our company was founded and continues to grow because of our dedication to the manufacturing of medical grade wire. Our mission is to continually improve the quality of our products, the speed and efficiency with which we respond to customers' requests, and our level of understanding of the materials we work with and recommend.

4.2 2014 Quality Goals

USA	2012	2013	2014	2015
Returned Material				
% of shipments	3.1%	3.0%	2.7%	3.1%
% of revenue	1.7%	1.0%	0.9%	0.8%
Documentation Complaints				
% of shipments	2.3%	2.0%	1.8%	2.5%
IRELAND	2012	2013	2014	2015
Returned Material				
% of shipments	1.2%	1.3%	1.3%	0.6%





5.0 Strengths

5.1 Significant Technological Strengths

Material knowledge and testing.

5.2 Outsourced Work

Electropolishing, vacuum annealing, and some coating.

5.3 Ship to Stock

Kanban System

5.4 Disaster Recovery Plan

5.5 Record Retention

55 years

6.0 Facilities

6.1 Three Shifts - 8 hours. Office Hours 8:00am - 4:30pm Eastern Time.

6.2 Have humidity, HEPA filtration system, no clean rooms.

6.3 Total Square Feet

476,575

6.4 Production Square Feet

376,116

6.5 80% capacity currently utilized.

6.6 Shut down schedule-major holidays and one day in February for Company Annual Meeting.

7.0 Miscellaneous

7.1 FIFO

7.2 SPC per customer request.

7.3 Inspection Equipment

Bench micrometers, uniaxial tensile testers, microscopes, hand resistance block.

If you have any additional questions or concerns, please contact your Fort Wayne Metals representative.