BD

1 Becton Drive – MC 226
Franklin Lakes, NJ 07417
www.bd.com

Quality Systems Self – Survey

SUPPLIER NAME: BD Medical – Medication Delivery Solutions	DATE: February 2025		
ADDRESS: 1 Becton Drive, MC 226	CITY: Franklin Lakes	STATE: NJ	ZIP CODE: 07417
TELEPHONE: 201-847-5283	FAX: 201-847-4855		

1. Business Information

1.1 Organization

President & CEO – BDX: Tom Polen	
President of Medical-MDS: Eric Borin	Vice President Quality Management Representative – MDS: Michele Wootten

1.2 Company Business Record

TYPE OF BUSINESS: Manufacturer of Finished Medical Devices	
DATE BUSINESS STARTED: 1897 (additional information available on BD.com)	PRIVATE OR PUBLIC HELD OWNERSHIP: Public

1.3 Financial Position

DUN & BRADSTREET NUMBER: 00-129-2192	ARE YOU A SUBSIDIARY OR DIVISION OF A CORPORATION: No
CORPORATE NAME: Becton Dickinson and Company	TOTAL SALES FOR CORPORATION: *(Financial information can be found within the BD Annual Report available on the Internet at: http://www.bd.com)*

2. Physical Plant/Facilities

Type of building(s):	Steel, Concrete block, Brick		
Square footage in manufacturing (give range):	Proprietary, varies by site		
Is adequate space available?	☒ Yes	☐ No
Is there a routine housekeeping schedule?	☒ Yes	☐ No
Is there a pest control program?	☒ Yes	☐ No

3. Quality Systems and Procedures

3.1 Quality Systems Requirements

Is the business ISO certified (ISO 9000 or ISO 13485)?	☒ Yes	☐ No
Are your manufacturing sites FDA registered?	☒ Yes	☐ No
Are your manufacturing sites ISO certified (ISO 9000 or ISO 13485)?	☒ Yes	☐ No
Is there a Quality Policy?	☒ Yes	☐ No
Is there a Quality Manual?	☒ Yes	☐ No
Does a separate QC Department exist?	☒ Yes	☐ No
Who does the QC/QA Department report to?	VP of Quality Management	
Is management review performed on a periodic basis?	☒ Yes	☐ No

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3.2	**Personnel**				
3.2.1	Total Number of employees: Approx. 50,000 Worldwide # in Administration: Varies # in Production/Manufacturing: Varies Number of Shifts / Days per week – Varies by site # in Quality: Varies				
3.2.2	Are employees trained on applicable regulations (ISO / QSR)?	☒ Yes		☐ No
3.2.3	Is there a training program to maintain job competency?	☒ Yes		☐ No
3.2.4	Are records of training maintained?	☒ Yes		☐ No

3.3	**Design Controls**				
3.3.1	Do written guidelines exist for design control?	☒ Yes		☐ No
3.3.2	Are new designs reviewed?	☒ Yes		☐ No
3.3.3	Does review adequately ensure that customer requirements are met?	☒ Yes		☐ No
3.3.4	Are discrepancies resolved prior to moving into production?	☒ Yes		☐ No
3.3.5	Does a design history file exist?	☒ Yes		☐ No
3.3.6	Is Risk Assessment performed (FMEA etc.)?	☒ Yes		☐ No

3.4	**Document Controls**				
3.4.1	Does a document control department exist?	☒ Yes		☐ No
3.4.2	Do documented specifications exist for all components, assemblies, and finished products?	☒ Yes		☐ No
3.4.3	Does a document change control system exist? *(includes change request, approvals, training, and implementation)*	☒ Yes		☐ No
3.4.4	A system exists to insure that only current revisions of document are available?	☒ Yes		☐ No

3.5	**Purchasing Controls**				
3.5.1	Do written guidelines exist for purchasing?	☒ Yes		☐ No
3.5.2	Is there a review of purchase orders?	☒ Yes		☐ No
3.5.3	Are discrepancies resolved prior to acceptance of a sales contract?	☒ Yes		☐ No
3.5.4	Is there a defined process for Supplier Selection, approval and on going evaluations?	☒ Yes		☐ No
3.5.5	Are records of supplier selection, approval and evaluations maintained?	☒ Yes		☐ No

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3.6 Product Identification and Traceability

3.6.1	Are lot/batch #'s assigned to materials/components and finished goods?	☒ Yes	☐ No
3.6.2	Are materials/components adequately controlled to ensure that only approved/acceptable material is released to production?	☒ Yes	☐ No
3.6.3	Is traceability from Raw Material to finished goods maintained?	☒ Yes	☐ No
3.6.4	Are Finished goods released based upon established acceptance criteria?	☒ Yes	☐ No

3.7 Manufacturing

3.7.1	Are specification and process changes verified and/or validated before implementation?	☒ Yes	☐ No
3.7.2	Are process changes approved and documented?	☒ Yes	☐ No
3.7.3	Are requirements in place for health, cleanliness, personal practices, and clothing of personnel if any of these could have an adverse effect on product quality?	☒ Yes	☐ No
3.7.4	Is manufacturing performed in Controlled Environment?	☒ Yes	☐ No
3.7.5	Is adequate contamination control in place?	☒ Yes	☐ No
3.7.6	Does documentation clearly state component/assembly numbers, descriptions, and necessary documents?	☒ Yes	☐ No

3.8 Acceptance Activities

3.8.1	Are test procedures readily available to appropriate personnel?	☒ Yes	☐ No
3.8.2	Are test results on file?	☒ Yes	☐ No
3.8.3	A stock rotation plan is in use (i.e. FIFO)	☒ Yes	☐ No
3.8.4.	Are criteria established for the acceptance and release of materials and finished goods?	☒ Yes	☐ No
3.8.5	Are sampling plan(s) based upon ANSI Z1.4 / Z 1.9 Standard	☒ Yes	☐ No

3.9 Calibration/Inspection, Measuring, Test Equipment

3.9.1	Does documented schedule for preventative maintenance exist?	☒ Yes	☐ No
3.9.2	Is Calibration performed on a periodic basis and records are kept on file?	☒ Yes	☐ No
3.9.3	Is measurement equipment used in production identified, maintained, and calibrated?	☒ Yes	☐ No
3.9.4	Are outside service(s) used for calibration where appropriate?	☒ Yes	☐ No
3.9.5	Are calibrations traceable to National/International standards (e.g. NIST)?	☒ Yes	☐ No

3.10 Nonconforming Product

3.10.1	Are there written procedures for disposing of or reworking rejected items?	☒ Yes	☐ No
3.10.2	Do controls exist to prevent the use and/or release of non-conforming materials/product?	☒ Yes	☐ No

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3.11 Corrective/Preventive Action

3.11.1	Is there a formal corrective/preventive action process and procedure?	☒ Yes	☐ No
3.11.2	Is effectiveness of CA/PA verified?	☒ Yes	☐ No

3.12 Labeling/Package Control

3.12.1	Is there a process for label control?	☒ Yes	☐ No

3.13 Internal Audits

3.13.1	Are internal audits of production activities performed on a routine basis?	☒ Yes	☐ No

3.14 Customer Complaints and Recall Capabilities

3.14.1	Is there a procedure for handling of customer complaints?	☒ Yes	☐ No
3.14.2	Are complaints investigated; and corrective actions taken as required?	☒ Yes	☐ No
3.14.3	Are records of complaints files kept? How long? Varies, depend on Regulatory requirements per region.	☒ Yes	☐ No
3.14.4	Is trend analysis performed?	☒ Yes	☐ No
3.14.5	Is there a company Recall/return plan in place?	☒ Yes	☐ No

3.15 Records

3.15.1	Does a DMR exist for each product?	☒ Yes	☐ No
3.15.2	Does a DHR exist for each lot/batch?	☒ Yes	☐ No
3.15.3	Are production documents collected and filed?	☒ Yes	☐ No
3.15.4	Is record retention period established?	☒ Yes	☐ No

3.16 Shipping/distribution records

3.16.1	Do records show:		
	a) Customer or distributor name and address?	☒ Yes	☐ No
	b) Date of shipments and quantity shipped?	☒ Yes	☐ No
	c) Lot or serial number of product shipped?	☒ Yes	☐ No
3.16.2	Are records for distribution maintained as per established retention period?	☒ Yes	☐ No

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