



# Change Notification BCN#1009

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**To:** CPC Biopharma Customers  
**From:** Nick Johnson, Senior Product Manager  
**Subject:** New Facility and Redundant Cleanroom Manufacturing Space  
Follow Up from June 10, 2019 Communication  
**Recommended Action:** None – For informational purposes only  
**Date:** March 9, 2020

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### Description of Change

CPC is building a new facility in Roseville, Minn. This facility will contain a redundant ISO Class 7 manufacturing cleanroom for biopharma product lines. This facility also will become the new shipping location for all CPC products, which will be reflected on future Letters of Certification.

### Affected Products

All CPC biopharma product lines. See Appendix A for affected products.

### Reason for Change

To accommodate CPC's continued growth and to provide redundant cleanroom manufacturing.

### Implementation Date

The new facility is expected to be completed Q3 2020. The redundant manufacturing cleanroom is expected to be operational Q4 2020.

### Additional Information

As noted above, the new cleanroom will provide redundant manufacturing. CPC's current biopharma cleanroom facility will continue to operate without change. This will ensure supply of product while the new cleanroom is being built and commissioned. There will be no interruptions of supply while the new facility is being qualified. After the new cleanroom is fully operational, the two cleanrooms will continue to operate simultaneously, which provides continued assurance of supply and capacity to grow in the future.

CPC will continue with quality system certifications to ISO 9001:2015 and ISO 13485:2016. All new manufacturing equipment qualified in the new cleanroom will go through CPC's IQ (Installation Qualification), OQ (Operational Qualification) and PQ (Performance Qualification) validation process.

The new ISO 7 cleanroom will be certified to ISO 14644 and 14698 standards. Following certification CPC will undergo a third party audit in alignment with the BPOG/RX360 single use joint audit program.

For additional information or questions, please email me at [nick.johnson@cpcworldwide.com](mailto:nick.johnson@cpcworldwide.com).

**Appendix A**

Product Line	Part Number
AQC	AQC17006
AQC	AQC17006HT
AQC	AQC17008
AQC	AQC17008HT
AQC	AQC22006
AQC	AQC22006HT
AQC	AQC22008
AQC	AQC22008HT
AQC	AQC33012
AQC	AQC33012HT
AQC	AQC44012
AQC	AQC44012HT
AQCDC	AQCDC17004
AQCDC	AQCDC17006
AQCDC	AQCDC17008
AQCDC	AQCDC22004
AQCDC	AQCDC22006
AQCDC	AQCDC22008
AQG	AQG17004
AQG	AQG17004HT
AQG	AQG17006
AQG	AQG17006HT
AQG	AQG17008
AQG	AQG17008HT
AQG	AQG17012
AQG	AQG17012HT
AQG	AQG33012
AQG	AQG33012HT
AQG	AQG33024
AQG	AQG33024HT
AQGSTC	AQGSTC2330900
AQGSTC	AQGSTC2330900HT
AQGSTC	AQGSTC2331000
AQGSTC	AQGSTC2331000HT
AQL	AQL17012
AQL	AQL17012HT

Product Line	Part Number
AQL	AQL17016
AQL	AQL17016HT
AQL	AQL33024
AQL	AQL33024HT
AQS	AQS17002
AQS	AQS17002HT
AQS	AQS17004
AQS	AQS17004HT
AQS	AQS17006
AQS	AQS17006HT
AQS	AQS17MPC
AQS	AQS17MPCHT
AQS	AQS33012
AQS	AQS33012HT
AQS	AQS33004
AQS	AQS33004HT
AQSTC	AQSTC2330900
AQSTC	AQSTC2330900HT
AQSTC	AQSTC2331000
AQSTC	AQSTC2331000HT
AQX	AQX17012
AQX	AQX17012HT
AQX	AQX17016
AQX	AQX17016HT
AQX	AQX22012
AQX	AQX22012HT
AQX	AQX22016
AQX	AQX22016HT
AQX	AQX33024
AQX	AQX33024HT
AQX	AQX44024
AQX	AQX44024HT
Back to back	MPC17C1703
Back to back	MPC17C1739
Back to back	MPC17X1703
Back to back	MPC17X1739

Product Line	Part Number
Back to back	MPX17X1703
Back to back	MPX17X1739
Back to back	MPX22X2239M
HFC	HFC22439M
HFC	HFC22639M
HFC	HFC22839M
HFC	HFC30039M
HFC	HFC32039
HFC	HFCD17439M
HFC	HFCD17639M
HFC	HFCD17839M
HFC	HFCD22439M
HFC	HFCD22639M
HFC	HFCD22839M
MPC03	MPC17002T03
MPC03	MPC17002T03B25
MPC03	MPC17004T03
MPC03	MPC17004T03B25
MPC03	MPC17006T03
MPC03	MPC17006T03B25
MPC03	MPC22002T03
MPC03	MPC22002T03B25
MPC03	MPC22002T03M
MPC03	MPC22002T03MB25
MPC03	MPC22004T03
MPC03	MPC22004T03B25
MPC03	MPC22004T03M
MPC03	MPC22004T03MB25
MPC03	MPC22006T03
MPC03	MPC22006T03B25
MPC03	MPC22006T03M
MPC03	MPC22006T03MB25
MPC03	MPC30003M
MPC03	MPC30003MB25
MPC03	MPC32003
MPC03	MPC32003B25
MPC03	MPCK17002T03
MPC03	MPCK17002T03B25
MPC03	MPCK17004T03

Product Line	Part Number
MPC03	MPCK17004T03B25
MPC03	MPCK17006T03
MPC03	MPCK17006T03B25
MPC03	MPCK32003
MPC03	MPCK32003B25
MPC39	MPC17002T39
MPC39	MPC17002T39B25
MPC39	MPC17004T39
MPC39	MPC17004T39B25
MPC39	MPC17006T39
MPC39	MPC17006T39B25
MPC39	MPC22002T39M
MPC39	MPC22002T39MB25
MPC39	MPC22004T39M
MPC39	MPC22004T39MB25
MPC39	MPC22006T39M
MPC39	MPC22006T39MB25
MPC39	MPC22C2239M
MPC39	MPC22X2239M
MPC39	MPC30039M
MPC39	MPC30039MB25
MPC39	MPC32039
MPC39	MPC32039B25
MPC39	MPC3301239
MPC39	MPC3301639
MPC39	MPC44012T39M
MPC39	MPC44024T39M
MPC39	MPCK17002T39
MPC39	MPCK17004T39
MPC39	MPCK17006T39
MPC39	MPCK17006T39B25
MPC39	MPCK32039
MPU	MPU171239
MPU	MPU221239M
MPU	MPU30039M
MPU	MPU32039
MPX03	MPX17803
MPX03	MPX17803B25
MPX03	MPX22603M



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Product Line	Part Number
MPX03	MPX22603MB25
MPX03	MPX22803M
MPX03	MPX22803MB25
MPX03	MPX30003M
MPX03	MPX30003MB25
MPX03	MPX32003
MPX03	MPX32003B25
MPX03	MPXK17803
MPX03	MPXK17803B25
MPX03	MPXK32003
MPX39	MPX17839
MPX39	MPX17839B25
MPX39	MPX22639M
MPX39	MPX22639MB25
MPX39	MPX22839M
MPX39	MPX22839MB25
MPX39	MPX30039M
MPX39	MPX30039MB25
MPX39	MPX32039
MPX39	MPX32039B25
MPX39	MPX3301239
MPX39	MPX44012T39M
MPX39	MPX44024T39M
MPX39	MPXK17839

Product Line	Part Number
MPX39	MPXK17839B25
MPX39	MPXK32039
MPX39	MPXK32039B25
SQC	SQCC221212M
SQC	SQCC222424M
SQC	SQCX221212M
SQC	SQCX222416M
SQC	SQCX222424M
STC	STC1700000
STC	STC1700100
STC	STC1700200
STC	STC1700300
STC	STC1700500
STC	STC1700600
STC	STC1700700
STC	STC1700800
STCII	STC2020000
STCII	STC2020100
STCII	STC2020200
STCII	STC2020300
STCII	STC2020900
STCII	STC2021000
Custom Items	Biopharma Custom Item Numbers

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End of List