

Compounding Pharmacy Questionnaire

Name of Compounding Pharmacy RC Compounding Services, LLC

Key contacts Ray Carlson (BSP Pharm, RPh, Owner, Pharmacist),
(330) 707-9001, rccompounding@sbcglobal.net

Locations 3030 Center Road Poland, Ohio 44514

When did you start compounding bevacizumab (Avastin) for retina injections? Around 2007

Number of bevacizumab doses annually prepared for intravitreal injections 100,000?

What quality control steps are taken to ensure that bevacizumab is safely compounded and distributed? RC Compounding is USP 797 compliant to compound sterile intrathecal, IV, IM, or sub-Q injections, and serum eye drops. To ensure that bevacizumab is safely compounded and distributed, RC compounding follows a rigorous cleaning and disinfection program. Following USP 979 guidelines, controls such as temperature, humidity, and air pressure are monitored and controlled daily. RC Compounding also complies with cGMP (current Good Manufacturing Practices) requirements.

Number of documented drug contaminations (ie recall of a lot or drug) from 2009 - 2014 0

If a case is reported, how do you investigate it? Ideally there would be no drug contaminations, but in the event, a recall would be initiated, and physicians would be notified of the situation.

Is an individual patient prescription required for your facility to dispense compounded Avastin? No

Is your company
accredited by Pharmacy
Compounding
Accreditation Board
(PCAB)?

No

Is your pharmacy licensed
as a traditional
compounding pharmacy?
If so, for which states?

Yes, RC compounding is a registered 503B facility and is
registered through the FDA.

Have you registered 503B
facility? If yes, please
answer the below
questions. If no, please
submit.

Yes, RC Compounding is a registered outsourcing facility.

Have you paid your
registration fee?

No

Is Avastin included in your
latest report to the
Secretary of HHS
identifying the drugs
compounded by your
facility?

Yes

Is your facility currently
complying with CGMP
requirements?

Yes

Have you been inspected
by FDA since registering
as a 503B facility?

No