

# THE R.F. NOZICK VALIDATION

## The R.F. Nozick Blood Bank Validation:

The R.F. Nozick OQ Validation Program was developed by a team of Blood Bank experts and laboratory clinicians who understood the need for an efficient system of validation that could save laboratories valuable time and resources while maintaining a high degree of patient safety.

With the R.F. Nozick OQ Validation Program, you can rest assured you are audit ready and operationally safe for your patients.

All Validations include our Matrix Analysis & Validation Report providing easy access to evidence of validation & corresponding regulatory requirements, making your next visit from an auditor as simple as possible.

## Why BC Solutions?

Following the International Society for Blood Transfusion (ISBT) guidelines for Validation and Maintaining a Validated State, BC Solutions has developed a unique methodology that reduces the total validation testing time by 50% to 60%, or as much as 500 labor hours.

In our Operational Qualification (OQ) Validation, Transfusion or Donor software is validated against a set of User Requirement Specifications (URS) which describe the processes and safety checks expected from all Blood Bank or Donor software applications.

Using worst case scenario testing, we stress the system by targeting high risk areas that could potentially cause harm or injury to patients or donors if undetected.

## Elements of the R.F. Nozick (OQ) Validation

- System Review
- Regulatory Requirements
- Risk Assessment
- Customized Test Plans
- Matrix Analysis & Validation Report

**Relationships**

**Quality**

*Innovation*