Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2023

Table of Contents

I. Summary

FDA requires reporting of certain deviations and unexpected events in manufacturing in accordance with 21 CFR 600.14, 606.171 or 1271.350(b). The following manufacturers, who had control over the product when an event associated with manufacturing (deviation or unexpected event) occurred, are required to submit Biological Product Deviation (BPD) reports to the Center for Biologics Evaluation and Research (CBER), if the safety, purity, or potency of a distributed product may be affected:

- Manufacturers of licensed biological products other than blood and blood components (licensed non-blood) who hold the biological product license [21 CFR 600.14];
- Licensed manufacturers of blood and blood components, including Source Plasma [21 CFR 606.171];
- Unlicensed registered blood establishments [21 CFR 606.171]; and
- Transfusion services [21 CFR 606.171].

In addition, manufacturers of nonreproductive Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) described in 21 CFR 1271.10 and regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 are required to submit HCT/P deviation reports to CBER, if the deviation or unexpected event involving a distributed product is related to a Core Current Good Tissue Practice requirement [21 CFR 1271.150(b)] and related to the prevention of communicable disease transmission or HCT/P contamination [21 CFR 1271.350(b)]. Hereafter, to improve the readability of this annual summary report, these products are collectively referred to as "361 HCT/Ps" rather than "nonreproductive HCT/Ps".

Detailed information concerning deviation reporting, including guidance documents on BPD reporting for blood and Source Plasma establishments (Ref. 1) and licensed manufacturers of biological products other than blood and blood components (Ref. 2), is available at Biological Product Deviation Guidances & Rules | FDA. A guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) is available at Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 | FDA.

This annual summary report provides an overview of the reports submitted during the fiscal year encompassing October 1, 2022, through September 30, 2023 (FY23), including detailed information regarding the number and types of deviation reports. Each firm responsible for reporting biological product and HCT/P deviations should use this information in evaluating their own deviation management program. We provide combined data submitted over the last three fiscal years to compare data and highlight changes. However, based on the limited data, we may not be able to determine the reason for changes to the number of reports submitted compared to the previous fiscal year.

Detailed information for blood and Source Plasma establishments can be found in Appendix 1; detailed information for licensed non-blood establishments can be found in Appendix 2; and detailed information for 361 HCT/P establishments can be found in Appendix 3. These appendices provide data to compare FY23 to FY22, whereas Tables 1 through 4 below also include comparative data for FY21. Previous summary reports are available at
Biological Product Deviation Reports Annual Summaries | FDA. Our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends.

Table 1 shows the number of reports submitted and the number of establishments who submitted reports each fiscal year for the past three years for each type of establishment. Although there were more than 16,258 reports submitted during FY23, this summary excludes data for deviation reports that did not meet the reporting requirements. We notified the reporter when a report was not required.

The total number of reports submitted in FY23 (16,258) increased 8% compared to FY22 (15,010). The total number of reporting establishments increased from 2,276 in FY22 to 2,475 in FY23. Compared to FY22, there were 203 more blood and Source Plasma establishments, 10 fewer manufacturers of licensed biological products other than blood and blood components, and six more 361 HCT/P manufacturers reporting in FY23.

Table 1 - Total Deviation Reports FY21 – FY23

Establishment Type	Number of Reporting Establishments			Total Reports Submitted			*Potential* Recalls		
	FY21	FY22	FY23	FY21	FY22	FY23	FY21	FY22	FY23
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	193(70*)	188(72*)	234(69*)	6,234	6,131	5,864	456	422	372
Unlicensed Blood Establishments[1]	340	328	330	2,589	2,429	2,637	10	13	8
Transfusion Services[2]	701	722	768	1,832	1,875	2,173	0	0	0
Source Plasma Establishments	774(15*)	875(17*)	984(18*)	3,166	3,848	4,904	0	0	0
Sub-Total	*2,008*	*2,113*	*2,316*	*13,821*	*14,283*	*15,578*	*466*	*435*	*380*
Licensed Non-Blood Manufacturers									
Allergenic	6(6*)	4(4*)	3(3*)	85	81	89	0	0	2
Blood Derivative	24(18*)	27(18*)	23(17*)	91	92	63	1	1	0
In Vitro Diagnostic	9(9*)	14(13*)	9(9*)	91	87	79	1	1	3
Vaccine	16(14*)	25(23*)	20(18*)	233	201	194	1	2	6
Gene Therapy Products	3(3*)	4(4*)	5(4*)	8	18	18	0	0	0
351 HCT/P	6(4*)	4(3*)	8(7*)	21	25	18	0	0	0
Sub-Total	*64 (54*)*	*78(65*)*	*68(58*)*	*529*	*504*	*461*	*3*	*4*	*11*
361 HCT/P Manufacturers									
Cellular HCT/P	46	44	53	136	134	134	0	0	0
Tissue HCT/P	34	41	38	70	89	85	11	27	33
Sub-Total	*80*	*85*	*91*	*206*	*223*	*219*	*11*	*27*	*33*
Total	**2,152**	**2,276**	**2,475**	**14,556**	**15,010**	**16,258**	**480**	**466**	**424**

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.
[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g., pooling, thawing, compatibility testing), may or may not register with FDA.
*Number of license holders; one or more establishments operate under one biologics license.

Blood and Source Plasma establishments submitted 96% of the total reports in FY23 and 1,295 more reports in FY23 compared to FY22 (Table 1). Table 2 shows the number of reports submitted each fiscal year for the past three years by each type of establishments. Licensed blood establishments submitted 38%, unlicensed registered blood establishments submitted 17%, transfusion services submitted 14%, and Source Plasma establishments submitted 31% of the total blood and Source Plasma reports in FY23. Compared to FY22, licensed blood establishments submitted 267 fewer reports (4.4% decrease), unlicensed registered blood establishments submitted 208 more reports (8.6% increase), transfusion

services submitted 298 more reports (15.9% increase), and Source Plasma establishments submitted 1,056 more reports (27.4% increase) in FY23.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
QC & Distribution	2,018	32.4%	2,328	38.0%	2,425	41.4%
Blood Collection	1,898	30.4%	1,785	29.1%	1,484	25.3%
Donor Screening	1,549	24.8%	1,118	18.2%	1,081	18.4%
Labeling	334	5.4%	326	5.3%	334	5.7%
Routine Testing	205	3.3%	230	3.8%	240	4.1%
Component Preparation	158	2.5%	230	3.8%	226	3.9%
Transfusion-Transmitted Infection Testing	47	0.8%	86	1.4%	63	1.1%
Donor Deferral	25	0.4%	28	0.5%	11	0.2%
Total	**6,234**	100%	**6,131**	100%	**5,864**	100%

Unlicensed Blood Establishments

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
QC & Distribution	1,598	61.7%	1,463	60.2%	1,607	60.9%
Routine Testing	392	15.1%	426	17.5%	475	18.0%
Labeling	489	18.9%	467	19.2%	455	17.3%
Component Preparation	75	2.9%	54	2.2%	76	2.9%
Transfusion-Transmitted Infection Testing	22	0.8%	5	0.2%	12	0.5%
Blood Collection	3	0.1%	6	0.2%	7	0.3%
Donor Screening	10	0.4%	6	0.2%	3	0.1%
Donor Deferral	0	0.0%	2	0.1%	2	<0.1%
Total	**2,589**	100%	**2,429**	100%	**2,637**	100%

Transfusion Services

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
QC & Distribution	995	54.3%	1,018	54.3%	1,196	55.0%
Routine Testing	528	28.8%	535	28.5%	607	27.9%
Labeling	303	16.5%	313	16.7%	361	16.6%
Component Preparation	3	0.2%	7	0.4%	8	0.4%
Transfusion-Transmitted Infection Testing*	3	0.2%	2	0.1%	1	<0.1%
Donor Screening	NA	NA	NA	NA	NA	NA
Blood Collection	NA	NA	NA	NA	NA	NA
Donor Deferral	NA	NA	NA	NA	NA	NA
Total	**1,832**	100%	**1,875**	100%	**2,173**	100%

**Bacterial detection testing*

Source Plasma Establishments

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
QC & Distribution	2,785	88.0%	3,433	89.2%	4,372	89.2%
Donor Screening	352	11.1%	395	10.3%	459	9.4%
Blood Collection	20	0.6%	11	0.3%	42	0.9%
Donor Deferral	8	0.3%	5	0.1%	24	0.5%
Transfusion-Transmitted Infection Testing	0	0.0%	4	0.1%	6	0.1%
Labeling	0	0.0%	0	0.0%	1	<0.1%
Component Preparation	1	<0.1%	0	0.0%	0	0.0%
Routine Testing	0	0.0%	0	0.0%	0	0.0%
Total	**3,166**	100%	**3,848**	100%	**4,904**	100%

Manufacturers of licensed non-blood products submitted 3% of the total reports in FY23 and 43 fewer reports in FY23 compared to FY22 (Table 1). Table 3 shows the number of reports submitted each fiscal year for the past three years for each type of manufacturer. Allergenic manufacturers submitted 19%, plasma derivative manufacturers submitted 14%, in-vitro diagnostic manufacturers submitted 17%, vaccine manufacturers submitted 42%, gene therapy product manufacturers submitted 4%, and licensed HCT/P manufacturers (351 HCT/Ps) submitted 4%, of the total licensed non-blood reports in FY23. Compared to FY22, allergenic manufacturers submitted eight more reports, plasma derivative manufacturers submitted 29 fewer reports, in-vitro diagnostic manufacturers submitted eight fewer reports, vaccine manufacturers submitted seven fewer reports, gene therapy product manufacturers submitted the same number of reports, and licensed HCT/P manufacturers submitted seven fewer reports in FY23.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Product Specifications	78	91.8%	78	96.3%	81	91.0%
Labeling	3	3.5%	2	2.5%	4	4.5%
Process Controls	1	1.2%	0	0.0%	2	2.%
Testing	0	0.0%	1	1.2%	1	1.1%
Incoming Material	2	2.4%	0	0.0%	1	1.1%
Quality Control & Distribution	1	1.2%	0	0.0%	0	0.0%
Total	**85**	100%	**81**	100%	**89**	100%

Blood Derivatives Manufacturers

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Product Specifications	33	36.2%	32	34.8%	20	31.7%
Process Controls	16	17.6%	20	21.7%	15	23.8%
Quality Control & Distribution	23	25.3%	19	20.7%	14	22.2%
Testing	6	6.6%	10	10.9%	8	12.7%
Labeling	8	8.8%	8	8.7%	4	6.4%
Incoming Material	5	5.5%	3	3.3%	2	3.2%
Total	**91**	100%	**92**	100%	**63**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Product Specifications	46	50.6%	24	27.6%	34	43.0%
Quality Control & Distribution	26	28.6%	30	34.5%	16	20.3%
Labeling	11	12.1%	17	19.5%	12	15.2%
Incoming Material	5	5.5%	7	8.0%	7	8.9%
Testing	2	2.2%	7	8.0%	6	7.6%
Process Controls	1	1.1%	2	2.3%	4	5.0%
Total	**91**	100 %	**87**	100%	**79**	100%

Vaccine Manufacturers

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Product Specifications	125	53.6%	86	42.8%	67	34.5%
Quality Control & Distribution	61	26.2%	43	21.4%	54	27.8%
Incoming Material	9	3.9%	25	12.4%	24	12.4%
Process Controls	15	6.4%	27	13.4%	18	9.3%
Labeling	11	4.7%	12	6.0%	17	8.8%
Testing	12	5.2%	8	4.0%	14	7.2%
Total	**233**	100%	**201**	100%	**194**	100%

Gene Therapy Product Manufactures

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Testing	0	0%	5	27.8%	9	50.0%
Process Controls	3	37.5%	1	5.6%	4	22.2%
Product Specifications	1	12.5%	6	33.3%	2	11.1%
Incoming Material	2	25.0%	3	16.7%	2	11.1%
Quality Control & Distribution	0	0%	2	11.1%	1	5.6%
Labeling	2	25.0%	1	5.6%	0	0.0%
Total	**8**	100%	**18**	100%	**18**	100%

Licensed HCT/P Manufacturers (351 HCT/Ps)

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Labeling	9	42.9%	20	80.0%	6	33.3%
Product Specifications	6	28.6%	2	8.0%	5	27.8%
Testing	2	9.5%	0	0.0%	5	27.8%
Process Controls	0	0%	2	8.0%	1	5.6%
Incoming Material	2	9.5%	1	4.0%	1	5.6%
Quality Control & Distribution	2	9.5%	0	0.0%	0	0.0%
Total	**21**	100%	**25**	100%	**18**	100%

Manufacturers of 361 HCT/Ps submitted 1% of the total reports in FY23 and four fewer reports in FY23 compared to FY22 (Table 1). Table 4 shows the number of reports submitted each fiscal year for the past three years by 361 HCT/P manufacturers, with the data displayed separately for cellular 361 HCT/P manufacturers (e.g., hematopoietic stem/progenitor cells) and tissue 361 HCT/P manufacturers (e.g., skin, musculoskeletal, cornea). Manufacturers of cellular 361 HCT/Ps submitted 61% and manufacturers of tissue 361 HCT/Ps submitted 39% of the total 361 HCT/P deviation reports in FY23. Compared to FY22, manufacturers of cellular 361 HCT/Ps submitted the same number of reports and manufacturers of tissue 361 HCT/Ps submitted six fewer reports in FY23.

Table 4 - 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Receipt, Pre-Distribution, Shipment & Distribution	102	75.0%	91	67.9%	100	74.6%
Processing & Processing Controls	16	11.8%	24	17.9%	16	11.9%
Facilities	1	0.7%	3	2.2%	6	4.5%
Supplies and Reagents	5	3.7%	5	3.7%	4	3.0%
Recovery	3	2.2%	1	0.7%	4	3.0%
Storage	3	2.2%	6	4.5%	2	1.5%
Donor Screening	2	1.5%	2	1.5%	1	0.7%
Equipment	0	0.0%	1	0.7%	1	0.7%
Environmental Control	2	1.5%	1	0.7%	0	0.0%
Donor Testing	1	0.7%	0	0.0%	0	0.0%
Donor Eligibility	1	0.7%	0	0.0%	0	0.0%
Labeling Controls	0	0.0%	0	0.0%	0	0.0%
Total	**136**	100%	**134**	100%	**134**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Receipt, Pre-Distribution, Shipment & Distribution	22	31.4%	18	20.2%	40	42.1%
Donor Screening	8	11.4%	7	7.9%	18	18.9%
Donor Testing	8	11.4%	11	12.4%	16	16.8%
Donor Eligibility	20	28.6%	37	41.6%	14	14.7%
Processing & Processing Controls	5	7.2%	11	12.4%	4	4.2%
Labeling Controls	2	2.9%	1	1.1%	2	2.1%
Storage	0	0.0%	1	1.1%	1	1.1%
Recovery	3	4.3%	2	2.2%	0	0.0%
Supplies and Reagents	1	1.4%	1	1.1%	0	0.0%
Environmental Control	0	0%	0	0.0%	0	0.0%
Equipment	1	1.4%	0	0.0%	0	0.0%
Facilities	0	0.0%	0	0.0%	0	0.0%
Total	**70**	100%	**89**	100%	**95**	100%

In FY23, there were no changes to the HCT/P Deviation Codes. The Blood BPD Codes were modified for consistency with the May 2022 guidance (Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by Blood and Blood Components | FDA. The Non-Blood BPD Codes were modified to consolidate the codes related to container, closure or device constituent part not meeting specification or found defective.

You may submit questions concerning this summary to CBER at bp_deviations@fda.hhs.gov or hctp_deviations@fda.hhs.gov.

II. References

1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments March 2020 https://www.fda.gov/media/70694/download
2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components October 2006 https://www.fda.gov/media/76309/download
3. Guidance for Industry - Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 September 2017 Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 | FDA

III. Appendices

1. BPD Reports Submitted by Blood and Source Plasma Establishments
2. BPD Reports Submitted by Licensed Non-Blood Manufacturers
3. HCT/P Reports Submitted by 361 HCT/P Manufacturers

Appendix 1. BPD Reports Submitted by Blood and Source Plasma Establishments

Tables 5 through 15 highlight the most frequent reports submitted in FY23 by each type of blood and Source Plasma establishment compared to reports submitted in FY22. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

1. Most Frequent BPD Reports Submitted by Licensed Blood Establishments[1]

Of the 5,864 reports submitted by licensed blood establishments in FY23 (Table 2), 2,425 reports (41.4%) involved quality control and distribution deviations or unexpected events (Table 5). The number of these reports increased 4% compared to FY22, which is an increase of 97 reports. There were 81 more reports submitted in FY23 compared to FY22 involving distributed units collected from a donor who subsequently tested confirmed positive for a relevant transfusion-transmitted infection. There were 19 more reports submitted in FY23 compared to FY22 involving a positive bacterial detection test result. *Cutibacterium acnes* was identified as the organism in 358 (63%) of the 566 reports regarding bacterial testing submitted in FY23.

Table 5 - Most Frequent BPD Reports - Quality Control & Distribution from Licensed Blood Establishments

QC & Distribution (QC)	FY22 (#)	FY22 (% of QC)	FY23 (#)	FY23 (% of QC)
Total QC Reports	**2,328**	**-**	**2,425**	
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***970***	***41.7%***	***1,051***	***43.3%***
Babesia	379	16.3%	383	15.8%
HBV	212	9.1%	270	11.1%
Anti-HBc	99	4.3%	163	6.7%
HCV	218	9.4%	190	7.8%
West Nile Virus	92	4.0%	133	5.5%
HIV	56	2.4%	63	2.6%
Chagas	8	0.3%	8	0.3%
Product identified as unsuitable due to positive testing; event discovered subsequent to distribution	***551***	***23.7%***	***572***	***23.6%***
Bacterial testing	547	23.5%	566	23.3%
Distribution of product that did not meet specifications	***514***	***22.1%***	***534***	***22.0%***
Product QC unacceptable, not performed, not documented, or incomplete	276	11.9%	241	9.9%
White Blood Cell count	129	5.5%	78	3.2%
Hematocrit/Hemoglobin	51	2.2%	72	3.0%
Platelet count	28	1.2%	26	1.1%
RBC recovery	29	1.2%	21	0.9%
Product in which specification, other than QC, was not met	48	2.1%	50	2.1%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	42	1.8%	69	2.8%
Outdated product	43	1.8%	30	1.2%
Shipping and storage	***198***	***8.5%***	***193***	***8.0%***

[1] Licensed blood establishments do not include Source Plasma establishments, for the purpose of this summary.

Of the 5,864 reports submitted by licensed blood establishments in FY23 (Table 2), 1,484 reports (25.3%) involved blood collection deviations or unexpected events (Table 6)**.** The number of these reports decreased 16.9% compared to FY22, which is a decrease of 301 reports. The number of reports involving clots or fibrin discovered in a product decreased 18.6%. There was a 24.2% decrease in reports of clots or fibrin discovered in frozen products after thawing (FY22-1,359; FY23-1,030).

Table 6 - Most Frequent BPD Reports – Blood Collection from Licensed Blood Establishments

Blood Collection (BC)	FY22 (#)	FY22 (% of BC)	FY23 (#)	FY23 (% of BC)
Total BC Reports	**1,785**	**-**	**1,484**	**-**
Collection process	***1,618***	***90.6%***	***1,322***	***89.1%***
Product contained clots or fibrin, not discovered prior to distribution	1543	86.4%	1,256	84.6%
Product hemolyzed, not discovered prior to distribution	60	3.4%	46	3.1%
Collection bag	***97***	***5.4%***	***101***	***6.8%***
Potential collection set defect	97	5.4%	98	6.6%
Sterility compromised	***67***	***3.8%***	***60***	***4.0%***
Bacterial contamination	30	1.7%	30	2.0%

Of the 5,864 reports submitted by licensed blood establishments in FY23 (Table 2), 1,081 reports (18.4%) involved donor screening deviations or unexpected events (Table 7). The number of these reports decreased 2.5% compared to FY22, which is a decrease of 28 reports.

Table 7 - Most Frequent BPD Reports - Donor Screening from Licensed Blood Establishments

Donor Screening (DS)	FY22 (#)	FY22 (% of DS)	FY23 (#)	FY23 (% of DS)
Total DS Reports	**1,118**	**-**	**1,081**	
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***942***	***84.3%***	***914***	***84.6%***
Donor not previously deferred	854	76.4%	849	78.5%
Donor previously deferred due to testing	41	3.7%	44	4.1%
Donor previously deferred due to history	47	4.2%	21	1.9%
Donor record incomplete or incorrect	***112***	10.0%	***125***	***11.6%***
Donor history questions	97	8.7%	118	10.9%
Incorrect gender specific question asked, or incorrect answer documented	81	7.2%	99	9.2%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***49***	***4.4%***	***36***	***3.3%***
Travel to or resided in malaria endemic area/history of malaria	19	1.7%	24	2.2%
Received antibiotics or medication which may adversely affect the product	19	1.7%	5	0.5%
Donor did not meet eligibility criteria	***11***	***1.0%***	***6***	***0.6%***

2. Most Frequent BPD Reports Submitted by Unlicensed Registered Blood Establishments

Of the 2,637 reports submitted by unlicensed registered blood establishments in FY23 (Table 2), 1,607 reports (60.9%) involved quality control and distribution deviations or unexpected events (Table 8)**.** The number of these reports increased 9.8% compared to FY22, which is an increase of 144 reports.

Table 8 - Most Frequent BPD Reports - Quality Control & Distribution from Unlicensed Registered Blood Establishments

QC & Distribution (QC)	FY22 (#)	FY22 (% of QC)	FY23 (#)	FY23 (% of QC)
Total QC Reports Received	**1,463**	**-**	***1,607***	
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,267***	***86.6%***	***1,414***	***88.0%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	616	42.1%	655	40.8%
Improper product selected for patient	147	10.0%	186	11.6%
Product not irradiated as required	167	11.4%	178	11.1%
Improper ABO or Rh type selected for patient	131	9.0%	121	7.5%
Procedure for issuing not performed or documented in accordance with specifications	63	4.3%	59	3.7%
Distribution of product that did not meet specifications	***142***	***9.7%***	***132***	***8.2%***
Product in which instrument QC, calibration, or validation unacceptable, incomplete, or not documented	41	2.8%	49	3.0%
Product in which specification, other than QC, was not met	43	2.9%	23	1.4%
Outdated product	25	1.7%	21	1.3%
Shipping and storage	***32***	***2.2%***	***51***	***3.2%***
No documentation that product was stored at appropriate temperature	11	0.8%	14	0.9%
Product was reissued without a record of proper temperature maintenance	9	0.6%	14	0.9%

Of the 2,637 reports submitted by unlicensed registered blood establishments in FY23 (Table 2), 475 reports (18.0%) involved routine testing deviations or unexpected events (Table 9). The number of these reports increased 11.5% compared to FY22, which was an increase of 49 reports. Compared to FY22, there were 42 more reports submitted in FY23 involving ABO and/or Rh testing.

Table 9 - Most Frequent BPD Reports - Routine Testing from Unlicensed Registered Blood Establishments

Routine Testing (RT)	FY22 (#)	FY22 (% of RT)	FY23 (#)	FY23 (% of RT)
Total RT Reports	**426**	**-**	**475**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***380***	***89.2%***	***435***	***91.6%***
ABO and/or Rh	70	16.4%	112	23.6%
Antigen typing	91	21.4%	100	21.1%
Antibody screening or identification	79	18.5%	93	19.6%
Compatibility	106	24.9%	88	18.5%
Sample (used for testing) identification	***46***	***10.8%***	***47***	***9.9%***
Sample used for testing was incorrectly or incompletely labeled	27	6.3%	27	5.7%
Unsuitable sample used for testing (e.g., too old)	12	2.8%	13	2.7%
Incorrect sample tested	7	1.6%	7	1.5%

Of the 2,637 reports submitted by unlicensed registered blood establishments in FY23 (Table 2), 455 reports (17.3%) involved labeling deviations or unexpected events (Table 10). Compared to FY22, there were 12 fewer reports submitted in FY23 involving labeling.

Table 10 - Most Frequent BPD Reports – Labeling from Unlicensed Registered Blood Establishments

Labeling (LA)	FY22 (#)	FY22 (% of LA)	FY23 (#)	FY23 (% of LA)
Total LA Reports Received	**467**	**-**	**455**	**-**
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***296***	***63.4%***	***260***	***57.1%***
Recipient identification incorrect or missing	123	26.3%	84	18.5%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	56	12.0%	63	13.8%
Expiration date or time extended or missing	21	4.5%	28	6.2%
Compatibility information incorrect or missing	20	4.3%	19	4.2%
Unit or pool number incorrect or missing	15	3.2%	12	2.6%
Antigen incorrect or missing	10	2.1%	12	2.6%
Combination of incorrect or missing information	7	1.5%	11	2.4%
Labels applied to blood unit incorrect or missing information	***171***	***36.6%***	***193***	***42.4%***
Expiration date or time extended or missing	89	19.1%	110	24.2%
Irradiation status incorrect or missing	22	4.7%	29	6.4%
Product type or code incorrect or missing	14	3.0%	16	3.5%
Combination of incorrect or missing information	11	2.4%	12	2.6%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 2,173 reports submitted by transfusion services in FY23 (Table 2), 1,196 reports (55.0%) involved quality control and distribution deviations or unexpected events (Table 11). The number of these reports increased 17.5% compared to FY22, which was an increase of 178 reports.

Table 11 - Most Frequent BPD Reports - Quality Control & Distribution from Transfusion Services

QC & Distribution (QC)	FY22 (#)	FY22 (% of QC)	FY23 (#)	FY23 (% of QC)
Total QC Reports Received	**1,018**	**-**	**1,196**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***913***	***89.8%***	***1,077***	***90.1%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	442	43.5%	545	45.6%
Product not irradiated as required	105	10.3%	126	10.5%
Improper ABO or Rh type selected for patient	87	8.6%	118	9.9%
Improper product selected for patient	92	9.0%	73	6.1%
Procedure for issuing not performed or documented in accordance with specifications	72	7.1%	68	5.7%
Distribution of product that did not meet specifications	***71***	***7.0%***	***92***	***7.7%***
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	29	2.9%	36	3.0%
Outdated product	29	2.9%	28	2.3%
Shipping and storage	***27***	***2.7%***	***26***	***2.2%***

Of the 2,173 reports submitted by transfusion services in FY23 (Table 2), 607 reports (27.9%) involved routine testing deviations or unexpected events (Table 12). The number of these reports increased 13.5% compared to FY22, which was an increase of 72 reports.

Table 12 - Most Frequent BPD Reports - Routine Testing from Transfusion Services

Routine Testing (RT)	FY22 (#)	FY22 (% of RT)	FY23 (#)	FY23 (% of RT)
Total RT Reports Received	**535**	**-**	**607**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***479***	***89.5%***	***553***	***91.1%***
Compatibility	135	25.2%	153	25.2%
Antibody screening or identification	103	19.3%	144	23.7%
Antigen typing	121	22.6%	119	19.6%
ABO and/or Rh typing	83	15.5%	98	16.1%
Sample (used for testing) identification	***56***	***10.5%***	***54***	***8.9%***
Sample used for testing was incorrectly or incompletely labeled	45	8.4%	34	5.6%
Unsuitable sample used for testing	6	1.1%	11	1.8%
Incorrect sample tested	5	0.9%	8	1.3%

Of the 2,173 reports submitted by transfusion services in FY23 (Table 2), 361 reports (16.6%) involved labeling deviations or unexpected events (Table 13). The number of these reports increased 15.3% compared to FY22, which was an increase of 48 reports.

Table 13 - Most Frequent BPD Reports - Labeling from Transfusion Services

Labeling (LA)	FY22 (#)	FY22 (% of LA)	FY23 (#)	FY23 (% of LA)
Total LA Reports Received	**313**	**-**	**361**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***236***	***75.4%***	***266***	***73.7%***
Recipient identification incorrect or missing	117	37.4%	108	29.9%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	35	11.2%	49	13.6%
Compatibility information incorrect or missing	7	2.2%	23	6.4%
Antigen incorrect or missing	11	3.5%	16	4.4%
Product volume incorrect or missing	7	2.2%	16	4.4%
Unit or pool number incorrect or missing	9	2.9%	15	4.2%
Product type or code incorrect or missing	12	3.8%	10	2.8%
Combination of incorrect or missing information	16	5.1%	10	2.8%
Expiration date or time extended or missing	12	3.8%	5	1.4%
Labels applied to blood unit incorrect or missing information	***77***	***24.6%***	***93***	***25.8%***
Expiration date or time extended or missing	41	13.1%	45	12.5%
Combination of incorrect or missing information	10	3.2%	16	4.4%
Product type or code incorrect or missing	9	2.9%	16	4.4%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 4,904 reports submitted by Source Plasma establishments in FY23 (Table 2), 4,372 reports (89.2%) involved quality control and distribution deviations or unexpected events (Table 14). The number of these reports increased 27.4% compared to FY22, which was an increase of 939 reports. The number of reports related to a donor subsequently testing positive for HBV or HIV increased from 1,089 and 620 in FY22 to 1,884 and 783 in FY23 respectively. The number of reports related to a donor subsequently testing positive for HCV decreased from 1,540 in FY22 to 1,453 in FY23.

Table 14 - Most Frequent BPD Reports - Quality Control & Distribution from Source Plasma Establishments

QC & Distribution (QC)	FY22 (#)	FY22 (% of QC)	FY23 (#)	FY23 (% of QC)
Total QC Reports Received	**3,433**	**-**	**4,372**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***3,259***	***94.9%***	***4,124***	***94.3%***
HBV	1,089	31.7%	1,884	43.1%
HCV	1,540	44.9%	1,453	33.2%
HIV	620	18.1%	783	17.9%
Distribution of product that did not meet specifications	***153***	***4.5%***	***235***	***5.4%***
Product identified as unsuitable due to a collection deviation or unexpected event	59	1.7%	97	2.2%
Product identified as unsuitable due to a donor screening deviation or unexpected event	33	1.0%	71	1.6%
Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event	31	0.9%	42	1.0%
Missing or positive Syphilis testing	15	0.4%	26	0.6%
Missing Syphilis, HIV, HBV, HCV testing	2	0.1%	10	0.2%
No record of negative test results on 2 occasions in the past 6 months	3	0.1%	4	0.1%
Failure to quarantine unit due to medical history	***20***	***0.6%***	***11***	***0.3%***

Of the 4,904 reports submitted by Source Plasma establishments in FY23 (Table 2), 459 reports (9.4%) involved donor screening deviations or unexpected events (Table 15). The number of these reports increased 16.2% compared to FY22, which was an increase of 64 reports. There were 38 more reports submitted in FY23 compared to FY22 involving a donor providing history which warranted deferral or follow up and was not deferred. Compared to FY22, there were 10 more reports involving donor history questions incorrect or incomplete. Compared to FY22, there were 12 more reports involving donor identification.

Table 15 - Most Frequent BPD Reports - Donor Screening from Source Plasma Establishments

Donor Screening (DS)	FY22 (#)	FY22 (% of DS)	FY23 (#)	FY23 (% of DS)
Total DS Reports Received	**395**	**-**	**459**	**-**
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***188***	***47.6%***	***226***	***49.2%***
Unacceptable address	115	29.1%	94	20.5%
Unreliable donor	17	4.3%	27	5.9%
Donor received tattoo and/or piercing	9	2.3%	25	5.4%
Donor record incomplete or incorrect	***163***	***41.3%***	***186***	***40.5%***
Donor history questions	124	31.4%	134	29.2%
Donor comprehension	84	21.3%	88	19.2%
Incorrect gender specific question asked or incorrect answer	37	9.4%	45	9.8%
Donor identification	39	9.9%	51	11.1%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***36***	***9.1%***	***41***	***8.9%***
Donor not previously deferred	22	5.6%	34	7.4%
Donor previously deferred due to history	14	3.5%	7	1.5%
Donor did not meet eligibility criteria	***8***	***2.0%***	***6***	***1.3%***
Medical history interview or physical assessment not performed or inadequate	7	1.8%	6	1.3%

Appendix 2. BPD Reports Submitted by Licensed Manufacturers of Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Tables 16 through 21 highlight the most frequent reports submitted in FY23 by each type of licensed non-blood manufacturer compared to reports submitted in FY22. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

Of the 89 reports submitted by allergenic manufacturers in FY23 (Table 3), 91% of the reports were related to product specifications (Table 16).

Table 16 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**81**	-	**89**	-
Product Specifications	***78***	***96.3%***	***81***	***91.0%***
Product specification not met; contains precipitate	74	91.4%	76	85.4%

Of the 63 reports submitted by plasma derivative manufacturers in FY23 (Table 3), 32% of the reports were related to product specifications, 24% were related to process controls, and 22% of the reports were related to quality control and distribution (Table 17).

Table 17 - Most Frequent BPD Reports Submitted by Plasma Derivative Manufacturers

Plasma Derivative Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**92**	-	**63**	-
Product Specifications	***32***	***34.8%***	***20***	***31.7%***
Stability testing failed	11	12.0%	8	12.7%
Appearance	3	3.3%	4	6.3%
Potency	5	5.4%	1	1.6%
Chemical analysis/purity	0	0%	1	1.6%
Component packaged with final product did not meet specifications	14	15.2%	8	12.7%
Broken/cracked vial	11	12.0%	8	12.7%
Processing Controls	***20***	***21.7%***	***15***	***23.8%***
Process/Procedure	16	17.4%	8	12.7%
Manufacturing or processing performed using incorrect parameters	0	0%	4	6.3%
Quality Control and Distribution	***19***	***20.7%***	***14***	***22.2%***
Packing; Broken or cracked vial/syringe	11	12.0%	11	17.5%

Of the 79 reports submitted by in-vitro diagnostic manufacturers in FY23 (Table 3), 43% of the reports were related to product specification, 20% of the reports were related to quality control and distribution, and 15% were related to labeling. The number of reports involving unexpected reactions in testing was 27 in FY21, decreased to six in FY22 and increased to 27 in FY23 (Table 18).

Table 18 - Most Frequent BPD Reports Submitted by In-Vitro Diagnostic Manufacturers

In-Vitro Diagnostic Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**87**	-	**79**	-
Product Specifications	***13***	***14.9%***	***34***	***43.0%***
Product specification not met; Unexpected positive, negative, or weak reactions in testing	6	6.9%	27	34.2%
Quality Control and Distribution	***30***	***34.5%***	***16***	***20.3%***
Packing	22	25.3%	11	13.9%
Labeling	***17***	***19.5%***	***12***	***15.2%***
Package insert	6	6.2%	4	5.1%
Multiple information	6	6.2%	4	5.1%
Product label	3	3.1%	4	5.1%
Incoming Material	***18***	***20.7%***	***7***	***8.9%***
Incoming container closure did not meet specifications or discovered defective	16	18.4%	4	5.1%

Of the 194 reports submitted by vaccine manufacturers in FY23 (Table 3), 35% of the reports were related to product specifications and 27.8% of the reports were related to quality control and distribution, and 12% of the reports were related to incoming material (Table 19). There were 12 more reports submitted in FY23 compared to FY22 involving broken or cracked vial/syringe. There was a change to the deviation codes in FY23 that resulted in more events captured under incoming material rather than product specifications. There were reports submitted in FY22 involving leaking vials that were not reported in FY23 because they were determined not reportable due to user error and not associated with manufacturing.

Table 19 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**201**	-	**194**	-
Product Specifications	***49***	***24.4%***	***67***	***34.5%***
Product specification not met	38	17.9%	47	24.2%
Appearance	36	18.9%	44	22.7%
Stability testing failed	9	4.5%	19	9.8%
Potency	7	3.5%	7	3.6%
Quality Control and Distribution	***43***	***21.4%***	***54***	***27.8%***
Packing; Broken or cracked vial/syringe	41	20.4%	53	27.3%
Incoming Material	***57***	***28.4%***	***24***	***12.4%***
Incoming container, closure or device constituent part did not meet specifications or discovered defective	56	27.8%	20	10.3%

Of the 18 reports submitted by gene therapy manufacturers in FY23 (Table 3), 50% of the reports were related to testing and 22% were related to process control (Table 20).

Table 20 - Most Frequent BPD Reports Submitted by Gene Therapy Manufacturers

Licensed Gene Therapy Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**18**	-	**18**	-
Testing *– not performed or not documented*	***5***	***27.8%***	***9***	***50.0%***
Potency	1	5.6%	4	22.2%
Purity	0	0%	3	16.7%
Safety	1	5.6%	1	5.6%
Sterility	0	0%	1	5.6%
Stability	3	16.7%	0	0%
Process Controls	**1**	**5.6%**	**4**	**22.2%**
Incoming Material	**6**	**33.3%**	**2**	**11.1%**
Source or raw material does not meet specifications or otherwise found to be unsuitable	**1**	**5.6%**	**2**	**11.1%**
Incoming container closure did not meet specifications or discovered defective	3	16.7%	0	0%
Product Specifications	**3**	16.7%	**2**	**11.1%**
Quality Control & Distribution	**2**	**11.1%**	**1**	**5.6%**
Labeling	**1**	**5.6%**	**0**	**0%**

Of the 18 reports submitted by licensed HCT/P manufacturers (351 HCT/Ps) in FY23 (Table 3), 33% of the reports were related to labeling and 28% were related to product specification (Table 21).

Table 21 - Most Frequent BPD Reports Submitted by Licensed HCT/P Manufacturers (351 HCT/Ps)

Licensed HCT/P Manufacturers (351 HCT/Ps)	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**25**	-	**18**	-
Labeling	***20***	***80.0%***	***6***	***33.3%***
Product label; incorrect/illegible; recipient identification	18	72.0%	6	33.3%
Product Specifications	***2***	***8.0%***	***5***	***27.8%***
Product specification not met; contaminated with microorganism	1	4.0%	5	27.8%
Testing	***0***	***0%***	***5***	***27.8%***
Safety; performed incorrectly	0	0%	4	22/2%
Incoming Material	***1***	***4.0%***	***1***	***5.6%***
Incoming container closure did not meet specifications or discovered defective	1	4.0%	1	5.6%
Source or raw material does not meet specifications or otherwise found to be unsuitable	1	4.0%	0	0%
Processing	***1***	***4.0%***	***1***	***5.6%***
Environmental monitoring excursions; environmental monitoring not performed or performed incorrectly	0	0%	***1***	***5.6%***

Appendix 3. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

Tables 22 and 23 highlight the most frequent reports submitted in FY23 by each type of 361 HCT/P manufacturer compared to reports submitted in FY22. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

Of the 134 reports submitted by cellular 361 HCT/P manufacturers in FY23 (Table 4), 75% of the reports involved receipt, pre-distribution, shipment, and distribution and 12% of the reports involved processing and process controls (Table 22).

Table 22 - Most Frequent HCT/P Deviation Reports Submitted by Cellular 361 HCT/Ps Manufacturers

Cellular 361 HCT/Ps Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**134**	-	**134**	-
Receipt, Pre-Distribution, Shipment & Distribution	***91***	***67.9%***	***100***	***74.6%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	89	66.4%	96	71.6%
Processing & Processing Controls	***24***	***17.9%***	***16***	***11.9%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	17	12.7%	11	8.2%
In-process controls; Not followed	7	5.2%	5	3.7%

Of the 95 reports submitted by tissue 361 HCT/P manufacturers in FY23 (Table 4), 42% of the reports involved receipt, pre-distribution, shipment, and distribution and 19% of the reports involved donor screening (Table 23).

Table 23 - Most Frequent HCT/P Deviation Reports Submitted by Tissue 361 HCT/Ps Manufacturers

Tissue 361 HCT/Ps Manufacturers	FY22 (#)	FY22 (%)	FY23 (#)	FY23 (%)
Total Reports	**89**	-	**95**	-
Receipt, Pre-Distribution, Shipment & Distribution	***18***	***20.2%***	***40***	***42.1%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	4	4.5%	22	23.2%
Inappropriate shipping conditions; Packaging	5	5.6%	14	14.7%
Donor Screening	***7***	***7.9%***	***18***	***18.9%***
Donor screening not performed or performed incorrectly	7	7.9%	18	18.9%
Donor medical history interview	6	6.7%	11	11.6%
Medical record review	1	1.1%	6	6.3%
Donor Testing	***11***	***12.4%***	***16***	***16.8%***
Unacceptable specimen tested; Donor incorrectly or not evaluated for plasma dilution	8	9.0%	13	13.7%
Testing not performed or documented when required, for	0	0%	2	2.1%
Treponema pallidum	0	0%	1	1.1%
Multiple tests – all testing	0	0%	1	1.1%
Donor Eligibility	***37***	***41.6%***	***14***	***14.7%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	29	32.6%	9	9.5%
Final autopsy results received post distribution	4	4.5%	3	3.2%