

Figure 3

**Process/Product
Failure Modes and Effects Analysis
(FMEA)**

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	S E V	Potential Causes	O C C	Current Controls	D E T	R P N	Actions Recommended	Resp.	Actions Taken	S E V	O C C	D E T	R P N
What is the Process Step	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause or effect occur?	What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode? Should include an SOP number.	How well can you detect causes or FMT?		What are the actions for reducing the occurrence of the Cause, or improving Detection? Should have actions only on high RPN's or easy fixes.	Whose Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? Be sure to include completion month/year				
Determine vaccine eligibility	Initial Eligibility	Patient is ineligible to receive vaccine	Patient cannot receive vaccine	9	Uncontrollable	1	Vaccine is only recommended to patients eligible to receive it	3	27	None	None	None				0
Lead with assertive recommendation	Patient Subjective Information (hesitant)	Recommendation increases patient's hesitancy	Patient elects to not receive vaccine	9	Pharmacist is not properly trained	7	None	9	567	Pharmacists receive training on how to address vaccine hesitant patients	Pharmacist	Pharmacists receive virtual and inperson training on how to handle hesitant patients (3/20)	9	3	3	81
Assess	Initial Eligibility	Patient is ineligible to receive vaccine	Patient cannot receive vaccine	9	Uncontrollable	1	Vaccine is only recommended to patients eligible to receive it	3	27	None	None	None				0
Plan	Time	Patient does not have enough time to receive vaccine	Patient cannot receive vaccine	7	Pharmacy is understaffed	3	None	5	105	None	None	None				0
Implement (Administer)	Pharmacist Experience	Pharmacist does not know how to address hesitancy	Patient elects to not receive vaccine	9	Pharmacist is not properly trained	7	None	9	567	Pharmacists receive training on how to address vaccine hesitant patients	Pharmacists receive training on how to address vaccine hesitant patients (3/20)	Pharmacists receive virtual and inperson training on how to handle hesitant patients (3/20)	9	3	3	81
Follow-up/Document	Patient Education	Patient does not receive any follow-up or counseling	Patient is misinformed	5	Pharmacist is too busy	3	None	3	45	None	None	None				0