

Root-Cause Analysis Workshop



- Some examples for discussion

Root-Cause Analysis Workshop (1)

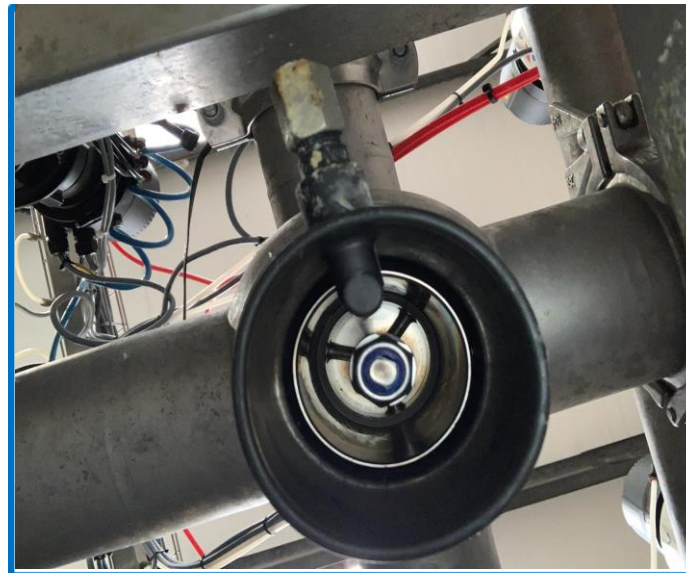


- **Typical approach for indicator species**
 - Sample in process and test at <10cfu/ml
 - Increase final product testing frequency <10cfu/ml
 - Swab in process plant equipment <1 cfu/ area
 - Swab in process environment <1 cfu/ area
 - Often unsuccessful.

- **Typical approach for pathogens**
 - As above
 - Often more successful
 - Sensitivity at Presence or absence in 25g

Root-Cause Analysis Workshop (2)

- Assumptions
 - automated valves
 - CIP Program
 - process program
 - SCADA ackn. OK
- Example
 - large creamery
 - raw milk valves
 - min Verification
 - old Validation



- Shelf-life issue in milk



Root-Cause Analysis Workshop (3)

	Vat No. vs E. coli																										
DOP	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55
01.06.24	10	0	0	0	0	0	0	0	0	110	20	240	50	0	30	150	100	70	1300	>3,000							
02.06.24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10		
03.06.24	0	10	0	0	0	20	0	0	390	150	1100	400	>3,000	1800	270	680	>3,000										
04.06.24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	20			
05.06.24	10	0	0	0	0	10	0	0	10	0	0	0	70	180	110	250	1800	>3,000									
06.06.24	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	30			
07.06.24	0	0	0	0	0	20	0	0	40	30	10	0	150				20	300	250								
08.06.24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10			

- What could have been done differently?

Assumptions

- first vats <10 cfu/g
 - no survival
- E. coli*** contamination
 - after Vat 29/30
- CIP Program
 - verified
 - validated

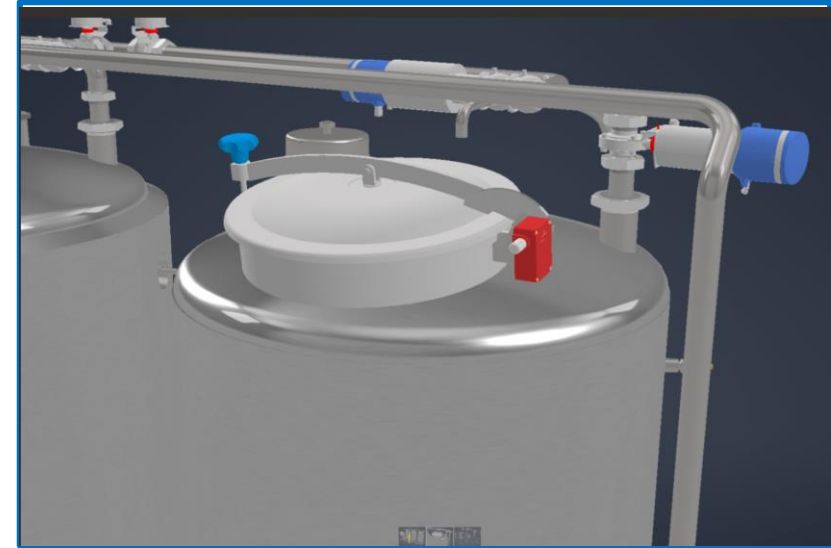
Example

- large creamery
- cheese
- Change - extended run
 - Not revalidated

Root-Cause Analysis Workshop (4)



3 Tank CIP set – RHS Final Rinse Tank



Root-Cause Analysis Workshop (4)



The Challenge of Root-Cause analysis

Open discussion