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EFFORTS TO IMPROVE THE PERFORMANCE OF THE QUALITY CONTROL (QC) SECTION OF PT. X USING THE SIX SIGMA METHOD TO FOCUS ON RISK MANAGEMENT

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Abstract: Introduction: The quality control (QC) process of a pharmaceutical company must be carried out following the Good Manufacturing Practices (CPOB) guidelines. Evaluation of the QC process in the pharmaceutical industry needs to be carried out to minimize notes and risks that could affect the final results of the tests carried out. Six Sigma and risk management can be used to identify defects and risks in the quality control processes carried out. The Six Sigma and risk management methods were used in this research to improve the performance of the pharmaceutical company PT. X in the Quality Control (QC) section. Method: The method used in this research is an observational method with primary and secondary data types. Data collection is carried out by interviews, observation, and documentation that focuses on defects and risks in the QC process. Data analysis uses the Six Sigma method with DMAIC stages and SPSS 25 statistical tests. Results: results of the risk management performance values of the PT QC section. X decreased by 7.7% with a DPMO value from 328,000 to 251,200 and the Six Sigma value increased from 1.95-sigma to 2.19-sigma. Statistical analysis using the SPSS 25 chi-square method shows a value of 0.005, which means there is a difference between the risk value before and after improvement. The results of the contingency coefficient test show a value of 0.803 (close to 1), which means the data obtained has a strong relationship. The data results show an increase in the performance of the Quality Control (QC) section of PT. X which can be seen from the risk value, DPMO, and sigma value.

Keywords: Six Sigma, risk management, DPMO

INTRODUCTION

The implementation of the CPOB Guidelines aims to continuously improve the quality of pharmaceutical/drug products and provide better protection for public health. Progressive steps need to be taken to address the development of the pharmaceutical industry in Indonesia so that the quality of medicines gains consumer recognition and trust, therefore, companies are required to improve product quality (BPOM 2006).

Every industry always has the goal of producing a product that has added value for consumers. To achieve its goals, an industry must experience and anticipate several risks. The challenge for management is to determine how far the risk can be handled so that it does not affect the value of a product (Widjaya 2013). Risk management is one approach that can be taken to manage risk. Risk management is a popular strategy that attempts to holistically evaluate and manage all risks faced by a company. According to Gupta (2011) in Jafari, M, Chadegani, A.A., and Biglari, V. (2011), the results of research on risk management practices in Indian companies state that effective risk management can improve organizational performance (Jafari et al. 2011).

Risk management is a systematic process for assessing, controlling, communicating, and reviewing risks to product quality throughout the life cycle (BPOM 2018). According to the Project Management Institute Body of Knowledge (1992), risk management is defined as a process related to the identification, analysis, and response to uncertainty including maximizing the results of positive events and minimizing the impact of adverse events (Burke 2007). The total weight of negative impacts (R) is equal to the probability of the event occurring (L) times the depth of the impact occurring (S). Evaluation of risk levels can be seen in Table 1.

Table 1. Risk Assessment Matrix

Likelihood / Severity	Negligible (1)	Minor (2)	Moderate (3)	Major (4)	Extrime (5)
Rare (1)	Low (1x1)	Low (1x2)	Low (1x3)	Low (1x4)	Medium (5x1)
Unlikely (2)	Low (2x1)	Low (2x2)	Medium (2x3)	Medium (2x4)	High (2x5)
Possible (3)	Low (3x1)	Medium (5x2)	Medium (3x3)	High (3x4)	High (3x5)
Likely (4)	Low (4x1)	Medium (5x2)	High (4x3)	High (4x4)	Very High (4x5)
Almost Certain (5)	Medium (5x1)	High (5x2)	High (5x3)	Very High (5x4)	Very High (5x5)

(Adapted from the AS/NZ 4360 Standard Risk Matrix and NHS QIS Risk Matrix)

Information :
Very High : Very high risk
High : High risk
Medium : Medium risk
Low : Low risk

Pharmaceutical companies must also be able to take advantage of opportunities and continuously improve and update their strategies. PT. X is a drug manufacturing company that produces pharmaceutical preparations that are widely used by consumers. The company's quality control is assessed by the extent to which there are still defective products above the tolerance limit of 2%. Six Sigma as an alternative to quality control principles, allows companies to make extraordinary improvements with actual breakthroughs. Six Sigma is an important tool for production management to maintain, improve, and maintain product quality and especially to achieve quality improvement towards zero defects (Almilia, Luciana, and Retrianasari 2007). Six Sigma is a statistical concept that measures a process related to defects or damage. Achieving Six Sigma means that the running process only produces 3.4 defects per million opportunities, in other words, the process runs almost perfectly. Sigma (the 18th letter of the Greek alphabet) is a term in statistics to denote standard deviation (Brue 2002). Six Sigma is a precise, focused, and effective implementation in proving principles and techniques regarding quality.

Pande (2002) states that Six Sigma is a new method or technique in terms of controlling and improving products where this system is very comprehensive and flexible to achieve, maintain, and maximize the success of a business, where this method is influenced by customer needs and the use of facts as well as data and paying close attention to the management system, improvement and reinvestment of a process (Pande, 2002).

Data processing was carried out following the Six Sigma principles and methodology which consists of five stages, namely DMAIC (Define, Measure, Analyze, Improve, Control) but in this research the Control stage was not carried out (Hapsari & Susatyo, 2015). In Six Sigma there is a cycle of 5 (five) DMAIC phases (Define, Measure, Analyze, Improve, Control), namely the process of continuous improvement towards the Six Sigma target. DMAIC is carried out systematically based on knowledge and facts. DMAIC is a closed-loop process that eliminates unproductive process steps, often focuses on new measurements, and applies technology to improve quality toward the Six Sigma target (Gaspersz, 2001).

Quality Control is that part of CPOB that is concerned with sampling, specifications, and testing, as well as with the organization, documentation, and release procedures which ensure that necessary and relevant tests have been carried out and that unapproved materials are not used and unapproved products are not sold or supplied before its quality is assessed and declared to meet requirements (BPOM 2018).

This research aims to analyze errors that may occur using the Six Sigma Method which is useful for improving performance in the Quality Control (QC) section of PT. X using Risk Management Analysis.

METHODS

The research will be carried out over a period of four months starting from February – May 2020 at the Pharmaceutical Industry PT. X in the Semarang Region, Central Java.

The type of research used is applied research with quantitative and qualitative data. Applied research is research carried out to apply, study, and evaluate the ability of a theory to be applied in solving practical problems in the field of everyday life. The research design in this research is the observational method. The types of data used in this research are primary data and secondary data, while the data collection methods used are interviews, observation, and documentation. The data taken focuses on the risks that occur in an activity by applying risk management methods. In this research, the data analysis used is the Six Sigma method which goes through five stages of analysis, namely define, measure, analyze, improve, and control and statistical analysis is carried out using SPSS 25 with the Chi-Square method to determine the difference between the 2 data obtained and the Contingency Coefficient test. to find out the relationship between the coefficients/types being tested.

Table 2. Research Instrument

No.	Process	Activities/Products/Services	C/ UC	Evaluate	
				L	D
1	Material Testing	Sampling and inspection of packaging materials			
		Sampling and inspection of raw materials			
2	Tool Testing	Washing laboratory testing equipment			
		Calibration/ Verification of tools			
		Care/maintenance of the tools used			
3	IPC (In Process Control)	Inspection of intermediate and bulk products (inner solids)			
		Inspection of bulk products (outer solid)			
		Bulk (liquid) product inspection			
		Inspection of bulk products (semi-solid)			
		Seamless IPC inspection			
4	Finished Product Inspection	Deep solid product			
		Outer solid product			
		Deep liquid product			
		External liquid products			
		Semi-solid product			
5	Stability Test	Checks 0, 3, 6, 9, 12, 18, 24, 36, 48, 60, 72			
6	Microbiological Test Examination	Microbiology testing (ALT, AKK, Pathogenic Bacteria)			
		Tool sterilization and digestion			
7	Reporting of Inspection Results	Recap of examination results			
		Print out the results of the inspection decision			
8	Preparation of secondary standards and reagents	Preparation of reagents and comparative standards, indicators			
9	Safety/PPE (Personal Protective Equipment)	Use of PPE for personnel during laboratory activities, to support personnel safety			
10	Operator/Personnel	Personnel activities and qualifications			

11	B3 waste processing	Processing waste remaining from QC testing (liquid, solid, semi-solid, precursor)
12	Sample left	Leftover sample procedure

RESULT AND DISCUSSION

Quality and Performance Evaluation

Evaluation of the quality and performance of PT's Quality Control (QC) section. X uses operational standards set by the company concerned. The standards used have been approved and meet the procedures implemented by CPOB and GLP (Good Laboratory Practice).

Risk Management Analysis

Risk Management is an effort to look for possible risks by evaluating the activities/processes carried out by a company and also taking follow-up actions to manage these risks. The evaluation was carried out to determine the level of risk in the QC process in the PT Pharmaceutical Industry. X by observing for + 1 month. From the observation results, it was found that 2 processes had a risk value of H (High), namely the IPC process for examining semi-solid bulk products and safety/PPE (Table 3. Define Stage).

Six Sigma Analysis

Six Sigma is a new method or technique for controlling and improving products where this system is very comprehensive and flexible to achieve, maintain, and maximize the processes carried out. The application of Six Sigma in this research focuses on the problem-solving process using DMAIC (Define, Measure, Analysis, Improve, Control).

Define Phase

The define phase is the phase for determining the problem, establishing QC requirements, and six sigma project objectives. The define phase in this research is related to the Risk Management method where this phase determines the type of assessment, assessment criteria and also observations regarding the type to be assessed.

From the results of the risk assessment, it can be said that the risk value in the QC sector of the Pharmaceutical Industry of PT. X ranges from 6-12, which includes Medium and High risk levels. The results of this assessment show that there is still the possibility of risks occurring that could have a high impact on the company. It is known that the lowest risk level in the assessment is at number 6 or medium level, a level where risks can still occur with a less high impact. Meanwhile, the highest risk value is 12 (high), this level is the level that must receive good management to reduce existing risks. The results of the assessment at the define stage can be seen in Table 3.

Table 3. Recap of Final Research Result

No.	Proses	Aktivitas/Produk/Jasa	C/ UC	FASE *DEFINE*				FASE *MEASURE*							FASE *ANALYZE*		FASE *IMPROVE*	FASE CONTROL										Usulan Perbaikan Jangka Panjang
								Evaluasi Risiko Sebelum										Evaluasi Risiko Setelah											
				L	D	R	Tingkat Risiko L, M, H, V	*Defect*	Persentase *Defect* (%)	Persentase *Yield* (%)	DPMO	Sigma	Ranking	Faktor Risiko	Risiko	Usulan Perbaikan	L	D	R	Tingkat Risiko L, M, H, V	*Defect*	Persentase *Defect* (%)	Persentase *Yield* (%)	DPMO	Sigma	Ranking	
1	Pengujian Material	Sampling dan pemeriksaan bahan kemas yang datang	UC	3	3	9	M	9	36	64	360.000	1,86	3	Human error saat sampling dan pemeriksaan, supplier tidak menghasilkan kualitas bahan yang sesuai	Hasil pemeriksaan tidak sesuai dengan spesifikasi	Meningkatkan ketelitian pengujian, memilih suplier dengan produk yang berkualitas	2	3	6	M	6	24	76	240.000	2,21	9	a. Melakukan kalibrasi secara teratur pada alat-alat mesin yang digunakan b. Mempertahankan pengadaan melalui suplier yang terpercaya dan melakukan audit suplier c. Training rutin pada personil QC d. Refresh mengenai CPOB, GLP dan Protap secara teratur/berkala
		Sampling dan pemeriksaan bahan baku yang datang		2	4	8	M	8	32	68	320.000	1,97	10				2	4	8	M	8	32	68	320.000	1,97	4	
2	Pengujian Alat	Pencucian alat - alat pengujian laboratorium	C	2	4	8	M	8	32	68	320.000	1,97	10	Alat tidak dicuci bersih	Komplain pelanggan karena kontaminasi produk	Penggunaan bahan pembersih yang berkualitas	1	4	4	L	4	16	84	160.000	2,49	19	
		Kalibrasi/ Verifikasi alat		2	4	8	M	8	32	68	320.000	1,97	10	Alat tidak dikalibrasi/ diverifikasi teratur		Kalibrasi alat sesuai jadwal	2	4	8	M	8	32	68	320.000	1,97	4	
		Perawatan/ pemelihaaan alat yang digunakan		2	4	8	M	8	32	68	320.000	1,97	10	Alat tidak dipelihara sesuai ketentuan		Pemeriksaan alat dan pemeliharaan yang teratur	2	4	8	M	8	32	68	320.000	1,97	4	
3	IPC (In Process Control)	Pemeriksaan produk antara dan ruahan (padat dalam)	C	3	3	9	M	9	36	64	360.000	1,86	3	Oven dan mesin pencetak tablet tidak bekerja dengan baik	Kadar air, bobot dan ukuran tablet tidak sesuai standar	Kalibrasi alat dan pelatihan penggunaan alat yang bersangkutan	3	3	9	M	9	36	64	360.000	1,86	2	
		Peneriksaan produk ruahan (padat luar)		3	3	9	M	9	36	64	360.000	1,86	3	Putaran homogenizer kurang lama	Kadar A, T, B tidak memenuhi standar		2	3	6	L	6	24	76	240.000	2,21	9	
		Pemeriksaan produk ruahan (cair)		2	3	6	M	6	24	76	240.000	2,21	21	Pengaturan alat *filling* kurang spesifik	Volume dan jumlah produksi tidak memenuhi standar		1	3	3	M	3	12	88	120.000	2,67	25	
		Peneriksaan produk ruahan (setengah padat)		4	3	12	H	12	48	52	480.000	1,55	1	Alat lama tidak dikalibrasi	Bobot memenuhi standar		4	3	12	H	12	48	52	480.000	1,55	1	
		Pemeriksaan IPC kemas		3	3	9	M	9	36	64	360.000	1,86	3	*Human error*, kesalahan alat *coding*, labeling salah	Identitas produk tidak sesuai persyaratan		2	3	6	M	6	24	76	240.000	2,21	9	
4	Pemeriksaan Produk Jadi	Produk padat dalam	C	2	4	8	M	8	32	68	320.000	1,97	10	*Human error*, alat tidak spesifik (belum dikalibrasi/diverifikasi), reagen	Produk jadi tidak memenuhi spesifikasi	Pelatihan ulang protap untuk meningkatkan ketelitian analis	1	4	4	L	4	16	84	160.000	2,49	19	
		Produk padat luar		2	4	8	M	8	32	68	320.000	1,97	10				1	4	4	L	4	16	84	160.000	2,49	19	
		Produk cair dalam		2	4	8	M	8	32	68	320.000	1,97	10				1	4	4	L	4	16	84	160.000	2,49	19	
		Produk cair luar		2	4	8	M	8	32	68	320.000	1,97	10				1	4	4	L	4	16	84	160.000	2,49	19	
		Produk setengah padat		2	4	8	M	8	32	68	320.000	1,97	10				1	4	4	L	4	16	84	160.000	2,49	19	
5	Pemeriksaan Uji Stabilitas	Pemeriksaan 0, 3, 6, 9, 12, 18, 24, 36, 48, 60, 72	C	3	3	9	M	9	36	64	360.000	1,86	3	Kondisi penyimpanan tidak sesuai	Hasil uji stabilitas ongoing tidak memenuhi syarat	Perluasan penyimpanan barang dalam masa uji stabilitas	2	3	6	M	6	24	76	240.000	2,21	9	
6	Pemeriksaan Uji Mirobiologi	Pengujian mikrobiologi (ALT, AKK, Bakteri Patogen)	C	2	3	6	M	6	24	76	240.000	2,21	21	*Human error*, alat dan media yang tidak steril	Hasil pemeriksaan mikro tidak sesuai dengan spesifikasi	Penjaminan sterilitas ruang dan personil	2	3	6	M	6	24	76	240.000	2,21	9	
		Sterilisasi alat dan Dekstruksi		2	3	6	M	6	24	76	240.000	2,21	21				2	3	6	M	6	24	76	240.000	2,21	9	
7	Pelaporan Hasil Pemeriksaan	Rekap hasil pemeriksaan	C	2	3	6	M	6	24	76	240.000	2,21	21	Ketidakdisiplinan personil, proses pelaporan yang tidak teratur dan hasil pemeriksaan yang tidak sesuai	Keterlambatan pelaporan hasil pemeriksaan	Pelaporan dibuat segera setelah dilakukan pemeriksaan	2	3	6	M	6	24	76	240.000	2,21	9	
		Print out hasil keputusan pemeriksaan	UC	2	3	6	M	6	24	76	240.000	2,21	21				2	3	6	M	6	24	76	240.000	2,21	9	
8	Pembuatan baku sekunder dan reagen	Pembuatan reagen dan baku pembanding, indikator	C	2	4	8	M	8	32	68	320.000	1,97	10	*Human error* , kondisi penyimpanan, kontaminasi	Larutan tidak dapat digunakan selama pemeriksaan	Kontrol pembuatan baku sekunder dan reagen (pelabelan jelas)	2	4	8	M	8	32	68	320.000	1,97	4	
9	Safety/APD (Alat Pelindung Diri)	Penggunaan APD pada personil saat aktivitas laboratorium, penunjang safety personil	C	4	3	12	H	12	48	52	480.000	1,55	1	Penggunaan APD yang tidak lengkap	Kecelakaan kerja, kontaminasi	Pelatihan mengenai bahaya tidak menggunakan APD	3	3	9	M	9	36	64	360.000	1,86	2	
10	Operator/ Personalia	Aktivitas dan kualifikasi personil	C	3	3	9	M	9	36	64	360.000	1,86	3	Ketidakdisiplinan personil	Proses pengujian, kegiatan QC tidak ter handle	Peningkatan kualitas personil dengan pelatihan yang diperlukan	2	3	6	M	6	24	76	240.000	2,21	9	
11	Pengolahan limbah B3	Pengolahan limbah sisa pengujian QC (cair, padat, semi padat, prekusor)	C	2	4	8	M	8	32	68	320.000	1,97	10	Pengolahan limbah tidak sesuai dengan protap	Pencemaran produk dan lingkungan	Pemantauan keamanan pengolahan limbah	2	4	8	M	8	32	68	320.000	1,97	4	
12	Sampel pertinggal	Prosedur sampel pertinggal	C	3	3	9	M	9	36	64	360.000	1,86	3	Penyimpanan sampel pertinggal tidak teratur	Kontaminasi	Perluasan penyimpanan sampel pertinggal	2	3	6	M	6	24	76	240.000	2,21	9	
	Rata - Rata					**8,2**		**8,2**	**32,8**	**67,2**	**328.000**	**1,95**			Rata - Rata					**6,28**		**6,28**	**25,1**	**74,88**	**251.200**	**2,19**		

Measure Phase

Assessment data obtained from the QC section of the Pharmaceutical Industry of PT. X indicates possible risks that occur during the quality control process. The steps in the measure phase are determining the average value of defect, yield, DMPO, and sigma as well as determining the sigma ranking from data on the probability of a risk occurring.

The risk management target is zero defects. The defect is a non-conformity or in this case, it is defined as the large possibility of a risk occurring. The Yield value means the probability that no risk will occur during the process being carried out. The calculation of the DPMO value is obtained by multiplying 10,000 defeat values, where the greater the DPMO value, the smaller the conversion in sigma. A low sigma value indicates that there is too much variation in a process. For example, in the IPC type of semi-solid bulk product inspection (ointment), a yield value of 52% was obtained from the target of 100%, which indicates that there are 48% defect values that need to be corrected to reduce existing risks. The DPMO is 480,000 and the sigma value is 1.55 in rank 1, meaning that improvement efforts need to be made to manage risks and as much as possible reduce the value of existing risks by reducing the level of errors that occur. If the error rate decreases, the risk level will automatically decrease (Table 3).

Analyze Phase

The Analyze phase is used to determine the causes/factors of possible risk occurrence which will be used to formulate improvements as a form of risk reduction effort. In this stage, the risk factors and the formulation of improvements or solutions use the RCA (Root Cause Analysis) and Fishbone Diagram tools.

Root Cause Analysis (RCA) is a popular tool used by companies running Lean Six Sigma. RCA is one of the tools used in problem-solving initiatives, to help teams find the root cause of the problem being faced. The stages in RCA include defining the problem, collecting data, identifying causes, identifying the root of the problem, and formulating solutions/improvements. The formulation of risk factors can be seen in Table 3 Analyze Phase.

From the results of the formulation of risk factors using the RCA method, the root of the problem will be obtained which is presented in the form of a fishbone diagram. The fishbone diagram groups the factors that cause risk into several points, namely factors that cause risk from the environment, method, machine, material and man. The Fishbone diagram can be seen in Figure 1.

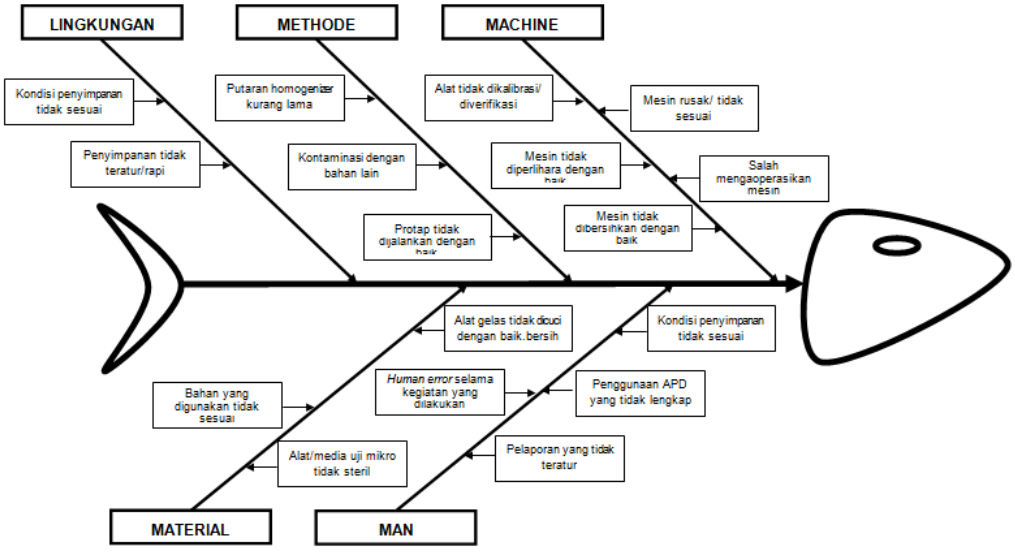

Figure 1. Fishbone Diagram

Risk factors that have been described and the root of the problem known are followed up with improvements. The improvements provided must be feasible and can reduce existing risks so that they can help improve the performance of the QC sector at PT. Ciubros Farma. The improvement proposals given are based on types with high levels of defects. The higher the defect value for an activity/process indicates that improvements need to be made immediately to prevent the risk of concern.

Improve Phase

The improvement phase is the stage where a proposed plan for improvement is carried out to prevent the causes of the problem from recurring to improve the quality of performance. From the analysis phase formulation, solutions/improvements were obtained and an FGD (Focus Group Discussion) was carried out. Focus Group Discussion (FGD) is a forum that focuses on a group to discuss a problem in an informal and relaxed atmosphere. FGD research results on initial risk values in the QC activities/processes of the Pharmaceutical Industry of PT. X.

The FGD activity explained the progress of the research being carried out and continued with CPOB training (How to Make Good Medicines) which focused on the field of Quality Control (QC/Quality Control). The training continued with material regarding GLP (Good Laboratory Practice) which explained various things about how to collaborate well. The improvement proposals submitted in the FGD can be seen in Table 3 Improve Phase.

Control Phase

The control phase is a continuation stage of improvement, at this stage proposals are made for controlling the results of the proposed improvements. In this phase, a re-assessment of each risk is carried out in the type of activity that takes place during the quality control process. Reassessment is carried out after + 3 weeks of implementing the improvements provided. The results of the reassessment after improvements have been carried out can be seen in Table 3 of the control phase. In the table it can be seen that the average risk/defect value before improvement was 8.2 and the average risk/defect value after improvement was 6.4, this shows that there was a change after the improvement.

The reduction in risks/defects after improvements were carried out shows that the improvements made through FGDs, training regarding CPOB, and GLP refreshes had a big influence in assessing risks/defects in the QC activities/processes of the PT Pharmaceutical Industry. X. In addition, a decrease in risk/defect also means that there is an increase in performance in the Quality Control (QC) section of the Pharmaceutical Industry of PT. X. Long-term improvements/controls need to be carried out to ensure the risk/defect value will not increase. The control phase that is carried out focuses on how to maintain improvements so that they continue stably.

Statistical Analysis

Data analysis was carried out to determine the differences between data before and after improvement. Analysis used SPSS 25 software with the chi-square method. Before being tested for chi-square, the data was tested for normality. Normality tests were carried out on data before and after improvement. The normality test results show that the risk value before improvement (Pre Risk Value) and the risk value after improvement (Post Risk Value) have normal data. The risk value before improvement is 0.000 < 0.05 and the risk value after improvement is 0.005 < 0.05.

The test was continued with a chi-square to see the difference in risk values before improvement and risk values after improvement. The results of the chi-square test show a value of 0.005 <0.05, which means there is a significant difference between the risk value before improvement and the risk value after improvement. Additional tests were carried out to determine whether there was a relationship between the two data using the Contingency Coefficient test. Contingency Coefficient is used to determine the

relationship between the risk value before improvement and the risk value after improvement. From the results of the Contingency Coefficient test, the results obtained show that the data has a high relationship where the value ranges from 0.803 (close to the value 1). From the statistical tests carried out it can be concluded that there is a difference and there is a close relationship between the risk value data before improvement and the risk value after improvement, this shows that there is an influence of the implementation of Six Sigma which focuses on risk management to improve the QC performance of the PT Pharmaceutical Industry. X.

CONCLUSION

Based on the results of the analysis and discussion of the performance of the QC section of the Pharmaceutical Industry of PT. X with the Six Sigma method and focuses on risk management, it is known that the results of the Risk Management Value Performance of the QC Pharmacy Industry Section of PT. X before the improvement was carried out and after the improvement was carried out decreased by 7.68%. DPMO value of PT Pharmaceutical Industry QC performance. X decreased from 328,000 to 251,200 and the sigma value increased from 1.95-sigma to 2.19-sigma. The statistical results of the Chi-Square and Contingency Coefficient tests show that there are differences and a close relationship between the risk values before and after the improvement.

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