

**Report of event of
Lean Six Sigma Green Belt
Certification Course
Date: 11/02/23 to 08/04/23**



P.E. Society's
MODERN COLLEGE OF PHARMACY,
Yamunanagar, Nigdi, Pune-44

What is Lean Six Sigma?



Lean Six Sigma Green Belt Certification Course

All students hereby inform that college has started "lean six sigma green belt certification course" at college campus from 11.02.2023 to 08.04.2023.

DR. K. S. SHAIKH
HEAD T & P




DR. P. D. CHAUDHARI
Principal

P. E. S. Modern College of Pharmacy
Sector No.21, Yamunanagar, Nigdi,
Pune - 411 044.

3. Lean Six Sigma Green Belt Certification Course (Notice)

**P. E. Society's
Modern College of Pharmacy, Nigdi, Pune.
Academic Year 2022-23**

Date: 22/05/2023

Department of Pharmaceutical Quality Assurance

Notice

This is to inform to all registered students of Lean Six Sigma Green Belt Value addition Course that your final examination is scheduled on 26th May 2023 from 11:00 am to 12:00 Pm. The seating arrangement will be in classroom no 3 to 6, first floor. All should present 15 min before at examination hall. All should carry college ID card.



Dr. K. S. Shaikh
(H.O.D. PQA)



Dr. P. D. Chaudhari
(Principal)

Copy to-
Academic Section
All HOD
Exam Section



LEAN SIX SIGMA GREEN BELT For QBD.

Department of Pharmaceutical Quality Assurance of PES's Modern College of Pharmacy, Nigdi, India in association with Mr. Santosh D. Awasarkar, Lean Six Sigma MBB, CEO-Founder @ Breath Apex IFP, India, under Centre For Pharma Business Excellence (CPBE) -CSSC, USA Accredited had conducted value addition certificate course of LEAN SIX SIGMA GREEN BELT For QBD.

Lean Six Sigma For Quality by Design (QBD) principles have been adopted by the USFDA for the discovery, development, and manufacture of drugs. Infact, global regulatory bodies- USFDA, EMEA made it mandatory for drug manufacturers to implement QBD Compliances into their new drug applications. ICH Guidelines-Q8, Q9, Q10 emphasizes QBD implementations. QBD principles in regulatory submissions ensures less hassle during review, fewer deficiencies leading to quicker approvals, fewer manufacturing problems, reduced number of post-market manufacturing supplements. QBD enhances ability to implement new technology that improves manufacturing without regulatory scrutiny. Set of expertise of Lean Six Sigma (DFSS-DMADV, DOE, SPC in QbD will create a synergy to deploy a structured statistical approach in designing & developing quality product. Hence, every global & Indian Pharma/ Biotech company need experts who can advise & deploy these high in demand skillsets.

The course was designed for Final Year B. Pharmacy and M.Pharm First year & Second Year. It was conducted in two batches. The first batch was conducted on following dates 11/02/2023, 12/2/2023, 18/02/2023, 19/02/2023, 11/03/2023. The second batch was conducted on 16/03/2023, 17/03/2023, 18/03/2023, 19/03/2023, 1/04/2023, 02/04/2023, 08/04/2023. During this course following 18 modules were conducted. Total 190 Students successfully completed the course

- What is QBD
- Principles of ICH Q8 CR2), (ICH Q9), (ICH Q10)
- Definition of QTPP, CQAs, CPPs, CMAs.
- Importance & History of Quality by Design (QbD)
- Lean Six Sigma. DMADV (Define, Measure, Analyze, Design, Verify) vs. DMAIC (Design, Measure, Analyze, Implement & Control);
- Determining Critical Quality Attributes (CQAs) based on Product Quality, Patient Safety & Efficacy. VOC Drill down, Critical-to- quality or Critical-to- safety, Critical-to- efficacy,



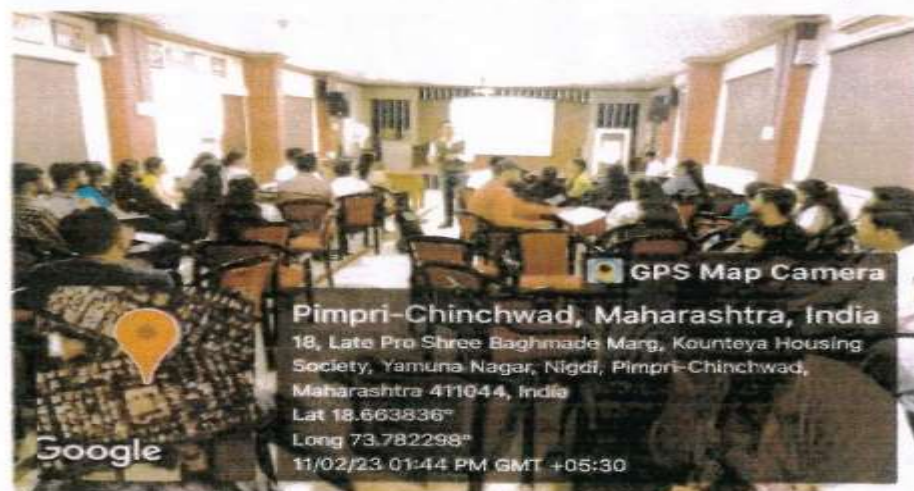
- High Level Process Mapping & Fishbone Diagram. Risk Analysis With Failure Modes Effects Analysis (FMEA) & Pareto Analysis.
- Process Lever Diagnostics Design. Project Charter, Problem Statement & Goal Statement, Project Scoping, Est. Project Benefit / Project QNS, Developing Performance Standard Documents.
- Project Communication: RACI Model (Responsible, Accountable, Consulted & Informed) FMEA, CI Matrix Driven Prioritization Of Critical Material Attributes (CMAs) & Critical Process Parameters (CPPs) With respect to CQAs. Principles.
- History & Types of DOE Designs, Full Factorial Design, Randomization, Replication, Repetition. Develop DoE Design Space, Deployment & Measurement of Responses(s).
- Development of regression model to Verify Design Space. Hypothesis testing, p value, Alpha value, Regression Coefficient, R Square Analysis, DOE Descriptive analysis: Pareto Plot, Main Effect Plot.
- Interaction Effect Plot & Cube Plots. Statistical Inferential Analysis: Analysis of Model Variance. CMAs / CPPs Optimization With Respect To CQAs. Process Improvement Statistical Validation With 2 Proportion Test.
- Determination Of Process Capability: Measurement Of Process Performance Indices- DPMO, DPU, DPO, SIGMA (LT & ST).
- Prediction Of Process Capability. Process Design Scale Up & Development Of Control Plan:- Monitoring Plan & Response Plan For CMAs, CPPs, & CQAs.
- Statistical Process Control: - Control Charts, Combined Control Charts, Selection & Application Of Attribute Control Charts: Control Charts (p chart, nP chart) . Process Control Validation & Determination of Process Capability.

During the conduct of course Mr.Santosh Awsarkar explained the various topics in detail. The course is very useful for Pharmacy professional. The students were very much engaged during this course. The final examination was conducted on 26/05/2023 at college. The college has taken feedback from each student about the course. The feedback was excellent about overall conduct of course. Every student who passed the examination was awarded with a certificate.




Batch I Day 1:

- Module: What is QBD.Principles of ICH Q8 CR2). (ICH Q9). (ICH Q10) .Definition of QTPP, CQAs, CPPs, CMAs. Importance & History of Quality by Design (QbD),Lean Six Sigma. DMADV (Define, Measure, Analyze, Design, Verify) vs. DMAIC (Design, Measure, Analyze, Implement & Control);



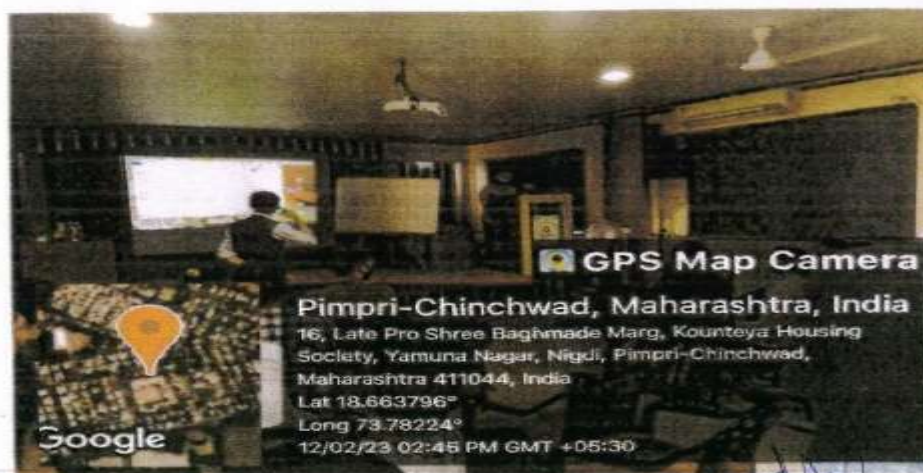
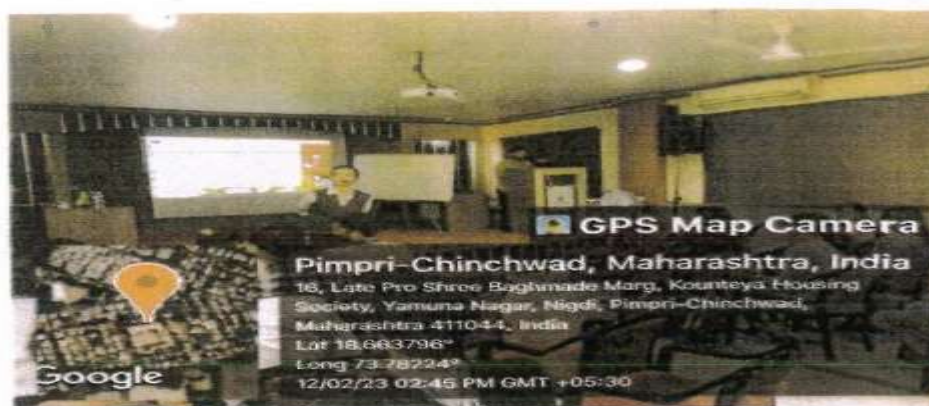
Mr. Santosh Awsarkar at the introductory session explaining important modules




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Batch I Day 2

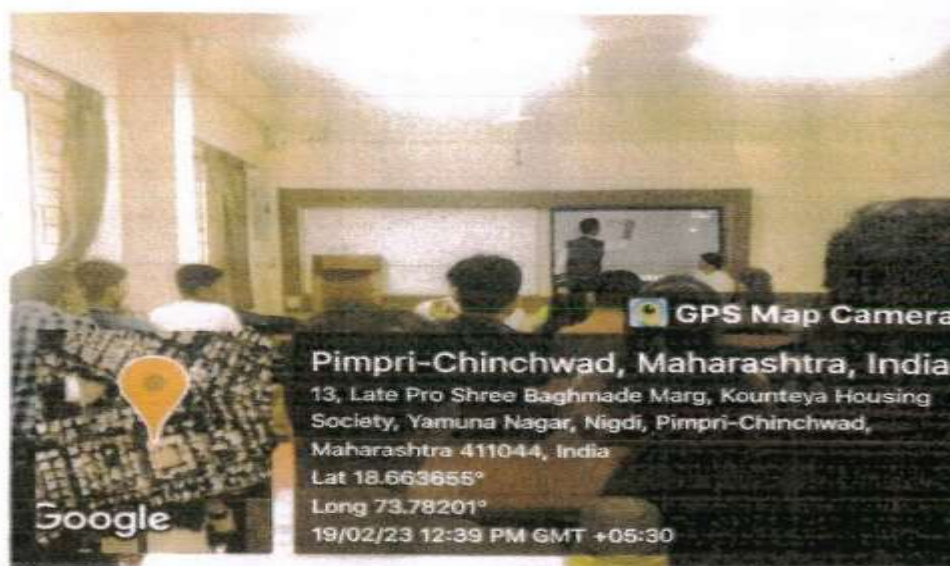
- Module Determining Critical Quality Attributes (CQAs) based on Product Quality Attributes (PQAs) such as Patient Safety & Efficacy, VOC Drill down, Critical-to- quality or Critical-to- safe (Critical-to- efficacy, Critical-to- delivery, Critical-to- cost), VOP, SIPOC, High Level Process Mapping & Fishbone Diagram, Risk Analysis With Failure Modes and Effects Analysis (FMEA) & Pareto Analysis, Process Level Diagnostics Design, Project Charter, Problem Statement & Goal Statement, Project Scoping, Est. Project Benefit / Project QNS, Developing Performance Standard Documents



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Batch I Day 3

- Module Project Communication: RACI Model (Responsible, Accountable, Consulted, Informed) FMEA, CI Matrix Driven Prioritization Of Critical Material Attributes (CMAs) & Critical Process Parameters (CPPs) With respect to CQAs. Principles, History & Types of DOE Designs, Full Factorial Design, Randomization, Replication, Repetitive Develop DoE Design Space, Deployment & Measurement of Responses(s) Development of regression model to Verify Design Space. Hypothesis testing, p value, Alpha value Regression Coefficient, R Square Analysis, DOE Descriptive analysis: Pareto Plot, Main Effect Plot

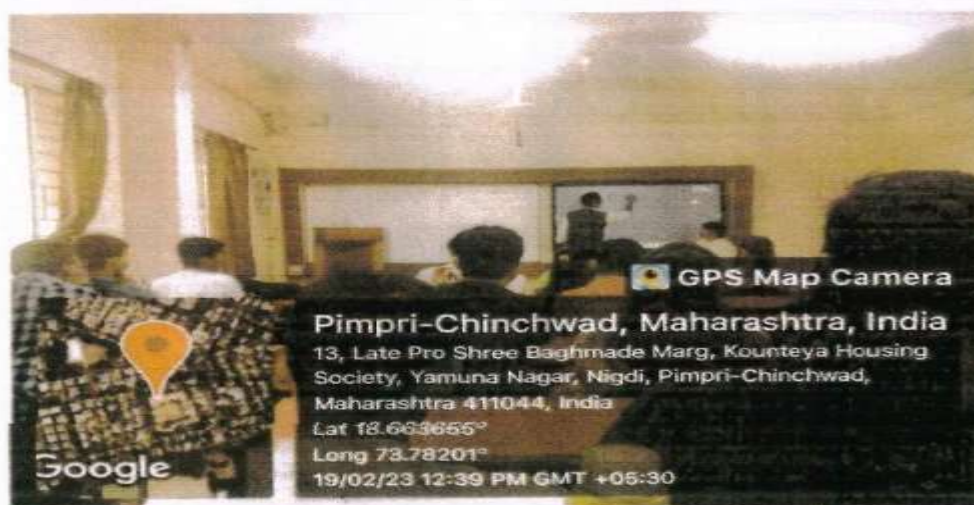
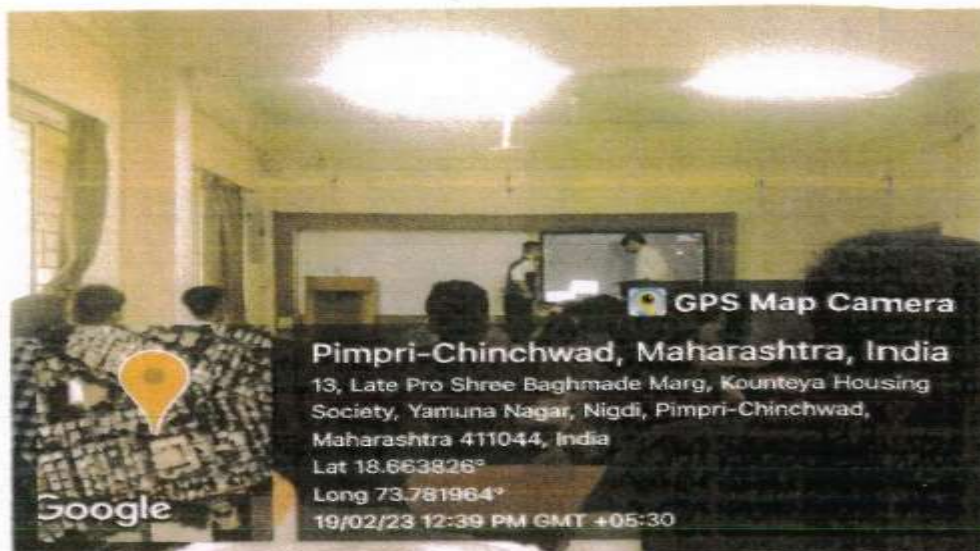



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Batch I Day 4

- Module Interaction Effect Plot & Cube Plots. Statistical Inferential Analysis: Analysis of Model Variance. CMAs / CPPs Optimization With Respect To CQAs. Process Improvement Statistical Validation With 2 Proportion Test.



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Batch I Day 5

Module: Determination Of Process Capability: Measurement Of Process Performance Indices- DPMO, DPU, DPO, SIGMA (LT & ST), Prediction Of Process Capability. Process Design Scale Up & Development Of Control Plan:- Monitoring Plan & Response Plan For CMAs, CPPs, & CQAs. Statistical Process Control: - Control Charts, Combined Control Charts, Selection & Application Of Attribute Control Charts: Control Charts (p chart, nP chart), Process Control Validation & Determination of Process Capability



[Signature]
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3. Lean Six Sigma Green Belt Certification Course (Attendance)

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<p style="text-align: center;">Approved by All India Council for Technical Education, New Delhi, Pharmacy Council of India, New Delhi, Directorate of Technical Education, Mumbai (MS), Permanently affiliated to Savitribai Phule Pune University, Pune & Approved under Section 2(F) & 2(B) of UGC Act - 1956</p>		
<p style="text-align: center;">Sector No. 21, Yamunanagar, Nigdi, Pune - 411 044. (M.S.) Tel. : 020-27661315 Fax : 020-27661314 E-mail : mcpnigdi44@gmail.com Website : www.mcop.org.in</p>		
<p>Prof. Dr. P. D. Chaudhari M.Pharm., Ph.D. Principal</p>		<p>Prof. Dr. Gajanan R. Ekbote M.S., M.M.A.M.S. Chairman, Business Council P.E.Society, Pune</p>
Sr. No	Name of Students	Sign
182	Sanjana Dole	
183	Shubham Humnabadkar	
184	Kartik Yenpure	
185	Kadambhari Shinde	
186	Lalit Sargar	
187	Samarth Shinde	
188	Dnyaneshwar Bende	
189	Krishna Halne	
190	Ganesh Kudke	
<div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  Dr. K. S. Shaikh HOD Dept of PQA </div> <div style="text-align: center;">  Mr. Santosh D. Awasarkar Director @ Pursullence, GBS, LLP </div> <div style="text-align: center;">  Dr. P. D. Chaudhari Principal </div> </div> <div style="text-align: right; margin-top: 10px;"> P. E. S. Modern College of Pharmacy Sector No. 21, Yamunanagar, Nigdi, Pune - 411 044. </div> <div style="text-align: center; margin-top: 20px;">  </div>		



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Principal

Prof. Dr. Gajanan R. Ishbote
M.S., M.N.A., M.S.
Chairman, Business Council
P.E.Society, Pune

Sr. No	Name of Students	Sign
144	Shivam Anil Chaudhari	<i>[Signature]</i>
145	Akansha Gangadhar Telang	<i>[Signature]</i>
146	Nitesh Rajendra Misal	<i>[Signature]</i>
147	Vimaji Goradwar	<i>[Signature]</i>
148	Siddhant Fulchand Gaikwad	<i>[Signature]</i>
149	Anjali Raju Wasule	<i>[Signature]</i>
150	Sarvade Ajinkya Anil	<i>[Signature]</i>
151	Meghana Nitin Patil	<i>[Signature]</i>
152	Shinde Shubhangi	<i>[Signature]</i>
153	Majgaonkar Manali Mahadev	<i>[Signature]</i>
154	Shraddha Shivalal Jadhav	<i>[Signature]</i>
155	Ashish Hanmant Shinde	<i>[Signature]</i>
156	Ajinkya Prakash Salve	<i>[Signature]</i>
157	Snehal Borude	<i>[Signature]</i>
158	Dipali Sanjay Thete	<i>[Signature]</i>
159	Harshal Sanjay Jagtap	<i>[Signature]</i>
160	Waghire Nikhil Ravindra	<i>[Signature]</i>
161	Priyanka Pandurang Tandlekar	<i>[Signature]</i>
162	Aparna Patil	<i>[Signature]</i>
163	Deshpande Shubham Sharad	<i>[Signature]</i>
164	Prajakta Bajrang Jagtap	<i>[Signature]</i>
165	Rutuja Udhav Gaikwad	<i>[Signature]</i>
166	Prathmesh Ashok Nale	<i>[Signature]</i>
167	Milind Gangadhar Dyagatwar	<i>[Signature]</i>
168	Pranali Anandrao Bhandare	<i>[Signature]</i>
169	Pradnya Ankush Khelbude	<i>[Signature]</i>
170	Niranjani Bharat Sonawane	<i>[Signature]</i>
171	Neha Prabhakar Shegokar	<i>[Signature]</i>
172	Tejaswini Shrimant Basate	<i>[Signature]</i>
173	Akanksha Praveen Amritkar	<i>[Signature]</i>
174	Rameshwar Shivraj Bhalke	<i>[Signature]</i>
175	Adwait Pranesh Tole	<i>[Signature]</i>
176	Shivhar Basavraj Shete	<i>[Signature]</i>
177	Kedar Jagtap	<i>[Signature]</i>
178	Akash Wakale	<i>[Signature]</i>
179	Nagesh Shirfule	<i>[Signature]</i>
180	Vaishnavi Sonone	<i>[Signature]</i>
181	Pranjali Inamdar	<i>[Signature]</i>





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Principal

Prof. Dr. Gajanan R. Eshole
B.S., M.A., M.S.
Chairman, Business Council
P.E.Society, Pune

Sr. No.	Name of Students	Sign
107	Harshal Rajesh Patil	Harshal
108	Vishal Annasaheb Vate	Vishal
109	Gaikwad Shraddha Prakashrao	Shraddha
110	Virendrakumar Madhukar Kambale	Virendra
111	Dnyaneshwari Ravindra Chopade	Dnyaneshwari
112	Prerana Ganesh Bambale	Prerana
113	Shilpa Sanjaykumar Biradar	Shilpa
114	Yashoda Navnath Tidke	Yashoda
115	Darshana Harishchandra Wani	Darshana
116	Jadhav Sidheshwar Lobhaji	Sidheshwar
117	Salunkhe Manisha Sanjay	Manisha
118	Sneha Satish Jadhav	Sneha
119	Sonal Sable	Sonal
120	Sonwane Sakshi Rajendra	Sakshi
121	Ghotekar Kalyani Shantaram	Kalyani
122	More Geetanjali Pandurang	Geetanjali
123	Vrushali Dattatray Kharate	Vrushali
124	Wadgave Pooja Bandappa	Pooja
125	Mayuri Shashikant Borbore	Mayuri
126	Khorde Rushikesh Vikram	Rushikesh
127	Wankhade Shetal Dinesh	Shetal
128	Akshata Balaji Biradar	Akshata
129	Khushboo Chaudhary	Khushboo
130	Vaishali Chitta	Vaishali
131	Rutuja Wayal	Rutuja
132	Ruchika Dayashankar Gupta	Ruchika
133	Samruddhi Ganesh Ingle	Samruddhi
134	Samiksha Sanjay Patokar	Samiksha
135	Akanksha Vijay Patil	Akanksha
136	Anushri Ashok Deulkar	Anushri
137	Pratik Balasaheb Suryawanshi	Pratik
138	Rutuja Satish Sonawane	Rutuja
139	Mahesh Mukund Pekamwar	Mahesh
140	Nikita Salunke	Nikita
141	Chavan Pooja Ramrao	Pooja
142	Yogish Dharmdas Garhwani	Yogish
143	Harshada Jitendra Chatter	Harshada





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Chairman, Business Council
P.E.Society, Pune

Sr. No	Name of Students	Sign
69	Chavhan Ankush Laxman	
70	Samadhan Kisan Tupe	
71	Vanve Shubham Balu	
72	Abhishek Maskare	
73	Abhishek Nagure	
74	Dnyaneshwar Rajendra Bembde	
75	Ajay Jagannath Dhapate	
76	Rahul Balasaheb Andhale	
77	Saurav Dilip Pawar	
78	Prathamesh Babanrao Badhe	
79	Gavali Kartik Rajendra	
80	Shrinath Shantinath Waghmare	
81	Akshay Deo	
82	Nikita Ganpat Pawar	
83	Raviraj Balasaheb Shinde	
84	Truptee Hiralal Banakar	
85	Nikhita Dattatray Kumbhar	
86	Rahul Ramdas Gambhire	
87	Ajay Prakash Patange	
88	Gayatri Jaising Gadekar	
89	Prajakta Dilip Tambe	
90	Sarvesh Sanjay Yeole	
91	Ganjure Kaveri Uddhav	
92	Sneha Nandkumar Rashinkar	
93	Priyanka Dadabhau Pote	
94	Gadhawe Trupti Bhausaheb	
95	Bhagirathi Narayan Bhale	
96	Mayuri Bharat Suryawanshi	
97	Geeta Anil Anawade	
98	Bhand Nitin Machhindra	
99	Desai Ganesh Shivanand	
100	Dhamankar Divya Madhukar	
101	Gaurav Arun Mahajan	
102	Tushar Mahesh Phalke	
103	Swapnil Tarate	
104	Pooja Bharat Salgar	
105	Vaishnavi Suresh More	
106	Deshpande Shubham Sharad	





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Chairman, Business Council
P.E.Society, Pune

Sr. No	Name of Students	Sign
31	Patil Ankita Pradeep	Ankita
32	Neha Barade	Neha
33	Shirsathsanket	Shirsath
34	Godbharle Amrut	Amrut
35	Shravani Pandurang Agalave	Shravani
36	Mohsin Masocri	Mohsin
37	Pratiksha Kantilal Hajare	Pratiksha
38	Dhanashri Vikram Katkar	Dhanashri
39	Nikita Gangaram Pawar	Nikita
40	Surabhi Shivaji Shinde	Surabhi
41	Kajal Sunil Pawade	Kajal
42	Sawant Pooja Nana	Sawant P.H.
43	Madhuri Ashok Gangurde	Madhuri
44	Animesh Ramkrushna Patil	Animesh
45	Nagalapur Pooja Prabhu	Pooja
46	Abhijit Balasaheb Deshmukh	Abhijit
47	Waghmare Shivshankar Ramrao	Waghmare
48	Abhijeet Prabhakar More	Abhijeet
49	Sonali Pandurang Nengule	Sonali
50	Purva Vernekar	Purva
51	Hake Pallavi Sudhakar	Hake
52	Pathan Adil	Pathan
53	Sampada Rakshe	Sampada
54	Asavari Ramesh Shinde	Asavari
55	Mayuri Mangilal More	Mayuri
56	Namrata Jaywant Daphale	Namrata
57	Damini Pradeep Shinde	Damini
58	Aditya Deveridra Chonde	Aditya
59	Shinde Utkarsha Namdevrao	Shinde
60	Harshali Vilas Sonawane	Harshali
61	Varsha Sunil Pawar	Varsha
62	Pratiksha Laxman Raut	Pratiksha
63	Gholap Abhijit Balasaheb	Gholap
64	Ganesh Dattatray Pore	Ganesh
65	Samiksha Surendra Agarkar	Samiksha
66	Magar Vaishnavi Sanjay	Magar
67	Gaikwad Anuj Vitthal	Anuj
68	Akshay Devidas Kalyan	Akshay





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Chairman, Business Council
P.E. Society, Pune

2022-23

Name of Course: LEAN SIX SIGMA GREEN BELT for QBD

Date: Batch A - 11th Feb 23 - 11th March 23

Batch B - 16th March 23 - 8th April 23

Course Code: NA

Course Duration: 32 hours

List of Students

Sr. No	Name of Students	Sign
1	Pavan Baburao Navghare	Pavan
2	Alfiya Mahibub Biradar	Alfiya
3	Mohini Bharat Jadhav	Mohini
4	Nikalje Rushikesh Nitin	Nikalje
5	Auti Mayuri Kashinath	Auti
6	Shinde Namrata Narsingrao	Shinde
7	Omkar Makey	Omkar
8	Shital Arun Susar	Shital
9	Radhika Somnath Vyavahare	Radhika
10	Aishwarya Shivaji Mahnagade	Aishwarya
11	Madhavi Sanjay Vikharankar	Madhavi
12	Renuka Gangadhar Zarekar	Renuka
13	Shaikh Fiza	Shaikh
14	Harshali Durgadas Dishware	Harshali
15	Sadhana Sandeep Pawar	Sadhana
16	Anjali Sunil Gaikwad	Anjali
17	Yaisangi Arpita Vitthal	Yaisangi
18	Rasika Prakash Babhulkar	Rasika
19	Priya Kisan Shete	Priya
20	Sharadha Shivaji Tikate	Sharadha
21	Waghmare Pradnya Sangram	Pradnya
22	Shraddha Dhanaji Shingade	Shraddha
23	Pratiksha Kondaware	Pratiksha
24	Anuradha Kamble	Anuradha
25	Gayatri Bhagwan Jagdale	Gayatri
26	Pratiksha Ramesh Madar	Pratiksha
27	Bafu Kailas Palekar	Bafu
28	Pavankumar Dattatraya Mare	Pavankumar
29	Kasture Snehal Hanamant	Kasture
30	Prajakta Bajrang Jagtap	Prajakta



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3. Lean Six Sigma Green Belt Certification Course (Sample certificate)





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