



Innovating for  
affordable healthcare

# Shilpa Medicare Limited (SML)

Q3 FY22 Results Presentation

# Disclaimer

Certain statements in this document may be forward-looking statements. Such forward looking statements are subject to certain risks and uncertainties like regulatory changes, local political or economic developments, and many other factors that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statements. Shilpa Medicare Limited (SML) will not be in any way responsible for any action taken based on such statements and undertakes no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.



***API Units, Raichur***



# Company Overview



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# Financial Performance

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# Abridged P&L Statement - Consolidated

(Rs. In Lakhs)

Particulars	Q3 Y22	Q3 FY21	Change (%)	9M FY22	9M FY21	Change (%)
<b>Total Income (I+II)</b>	<b>27,778</b>	<b>19,986</b>	<b>39</b>	<b>81,368</b>	<b>71,634</b>	<b>14</b>
I. Total Revenue from Operations (A+B+C+D)	27,230	19,125	42	80,493	69,305	16
•API (A)	18,195	13,533	34	50,216	46,128	9
•Formulations (B)	7,823	4,071	92	25,715	18,048	42
•Service Revenue / Product License Fees (C)	711	1,185	(40)	2,876	3,018	(5)
•Others (D)	501	337	49	1,686	2,112	(20)
II. Other income	548	861	(36)	875	2,329	(62)
Total Expenditure	22,724	17,028	33	67,487	53,765	26
<b>EBITDA</b>	<b>5,054</b>	<b>2,958</b>	<b>71</b>	<b>13,881</b>	<b>17,869</b>	<b>(22)</b>
<i>EBITDA margin (%)</i>	<i>18%</i>	<i>15%</i>		<i>17%</i>	<i>25%</i>	
Exceptional Income	-	-	-	891	6,084	(85)
<b>PBT</b>	<b>1,996</b>	<b>1,106</b>	<b>81</b>	<b>5,845</b>	<b>18,803</b>	<b>(69)</b>
<b>PAT</b>	<b>1,025</b>	<b>814</b>	<b>26</b>	<b>3,363</b>	<b>13,998</b>	<b>(76)</b>
Share of Profit/(Loss) of Non-Controlling Interest	(73)	(47)	-	(255)	(65)	292
<b>PAT after Share of profit/(loss) of Non controlling interest</b>	<b>956</b>	<b>767</b>	<b>25</b>	<b>3,111</b>	<b>13,936</b>	<b>(78)</b>

# Abridged P&L Statement - Standalone

(Rs. In Lakhs)

Particulars	Q3 FY22	Q3 FY21	Change (%)	9M FY22	9M FY21	Change (%)
<b>Total Income (I+II)</b>	<b>28,964</b>	<b>17,990</b>	<b>61</b>	<b>83,476</b>	<b>66,938</b>	<b>25</b>
I. Total Revenue from Operations (A+B+C+D)	27,664	17,129	62	80,284	65,061	23
•API (A)	18,195	12,782	42	50,216	43,998	14
•Formulations (B)	8,276	3,509	136	26,895	16,893	59
•Service Revenue / Product License Fees (C)	383	502	(24)	1,487	2,053	(28)
•Others (D)	810	337	140	1,686	2,118	(20)
II. Other income	1,300	861	51	3,192	1,876	70
<b>Total Expenditure</b>	<b>22,008</b>	<b>14,061</b>	<b>57</b>	<b>64,204</b>	<b>46,095</b>	<b>39</b>
<b>EBITDA</b>	<b>6,956</b>	<b>3,929</b>	<b>77</b>	<b>19,272</b>	<b>20,842</b>	<b>(8)</b>
<i>EBITDA margin</i>	<i>24%</i>	<i>22%</i>		<i>23%</i>	<i>31%</i>	
Exceptional Income	-	-	-	891	5,295	-
<b>PBT</b>	<b>4,835</b>	<b>2,487</b>	<b>94</b>	<b>14,078</b>	<b>22,031</b>	<b>(36)</b>
<b>PAT</b>	<b>3,677</b>	<b>1,687</b>	<b>118</b>	<b>10,554</b>	<b>15,780</b>	<b>(33)</b>

In relation to the import alert issued by the USFDA for the Jadcherla unit, the Company has initiated extensive remedial measures. The incremental costs incurred on account of the USFDA import alert is Rs 474 Lakhs in Q3 FY22 & Rs. 2,760 Lakhs

*Commenting on Q3 FY'22 performance, Mr. Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said,*

“Momentum in API business continues to improve in line with the measures we have taken, which is heartening. We have a deep pipeline of products that will help us maintain a positive outlook in this segment. In Formulation business, we are making progress in our engagement with the regulator and simultaneously have been carrying out new filings. Our team has been working collaboratively with the external consultants in order to achieve remediation. Meanwhile I am happy to share that we have successfully implemented site transfer for 2 products de-risking our business from single site dependency. We remain committed to normalize our US market operations at the earliest while we continue to enhance our reach in other key geographies.

I am pleased to share that we are working with Mylab Discovery Solutions Pvt Ltd to manufacture ‘Sputnik Light Drug Substance’ for them. Along with this we have initiated our manufacturing arrangements for the manufacture of ZyCoV-D. Additionally, we have made healthy progress on our own portfolio of products with very robust results in our clinical & animal trials for Adalimumab & Aflibercept respectively.

In a another significant development during the quarter, we have successfully raised Rs. 297 cr. through private placement of our shares to marquee investors. This fund raise has helped us in correcting the leverage position of the company while continuing with our growth impetus.”





# Discussion of API Segment

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## Key strengths of the business

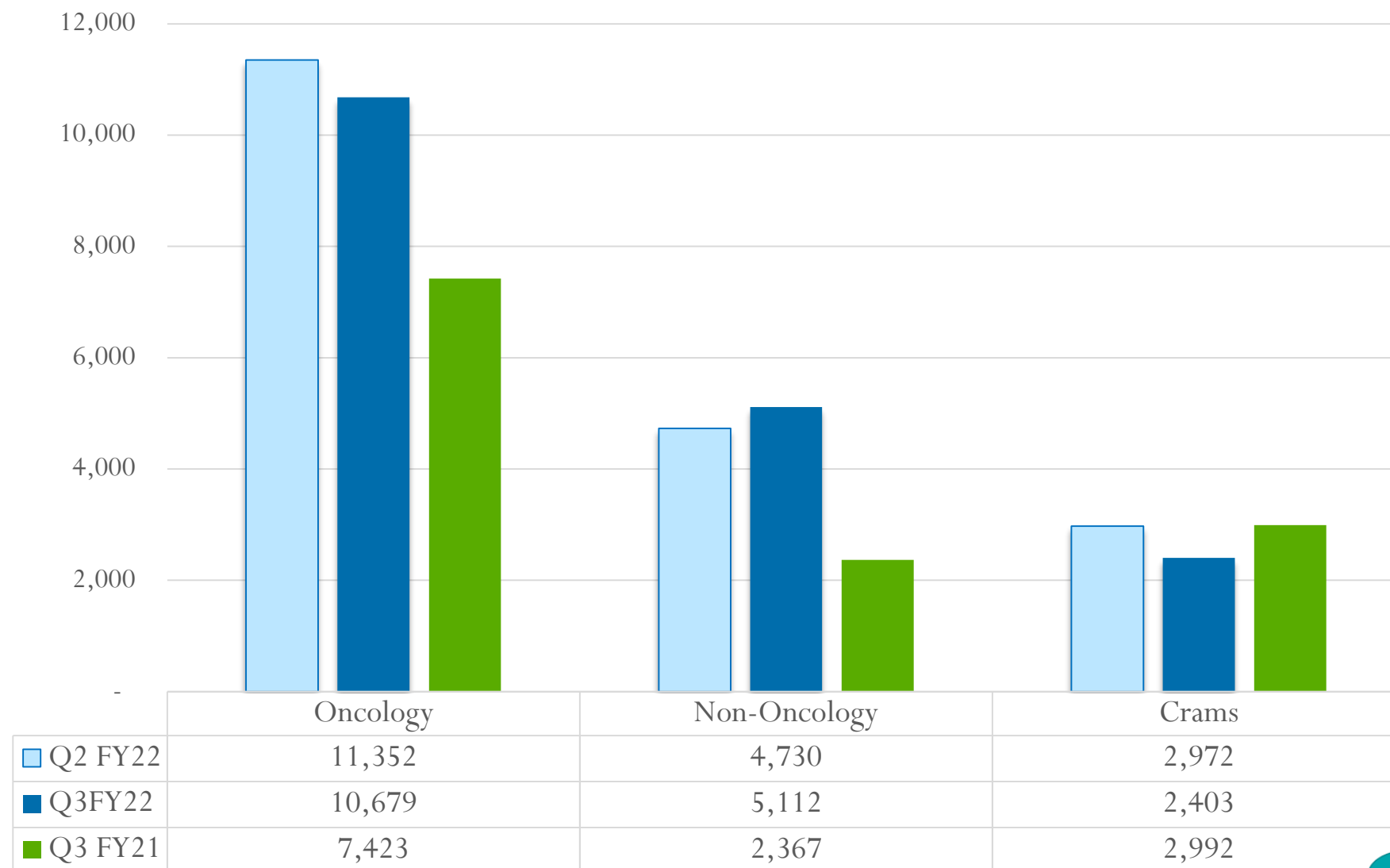
- Wide range of Oncology & Non oncology niche product portfolio
- Building capacity & capability to improve efficiency & reach
- Continuous improvement in process, operation & development to improve the yield , quality & compliance to maintain leadership position in key molecules
- Positioned business development teams in all the regions globally
- Strong R&D with focus on difficult to synthesize products including development of newer business segments

## Way forward

- Separate business under a separate subsidiary to provide focused approach resulting in better operating efficiency with fund raising opportunity in the segregated business either from strategic investors through private placement or from investors at large through public issue
- Greater impetus to specialty areas of CDMO, Peptides, Polymers & intermediate with early success signs
- Continuous efforts on process optimization & efficiency improvement

Rs. In Lakhs

# API REVENUE HIGHLIGHTS



# Product wise DMF filings as on December 31, 2021

Name of the API	US FDA	EU/ EMEA	TPD-Canada	PMDA Japan	TGA & Medsafe-NZ	EDQM	KFDA Korea	GCC & ROW	WHO Market
Ambroxol HCl				✓		✓	✓	✓	
Azacitidine	✓	✓	✓	✓			✓	✓	
Bicalutamide	✓	✓	✓	✓			✓	✓	
Bendamustine HCl	✓	✓	✓		✓		✓	✓	
Bortezomib	✓	✓	✓				✓	✓	
Busulfan	✓		✓	✓	✓	✓	✓	✓	
Capecitabine	✓	✓	✓	✓	✓	✓	✓	✓	
Decitabine	✓		✓				✓	✓	
Erlotinib HCl	✓	✓			✓		✓	✓	
Fingolimod HCl	✓	✓	✓		✓	✓		✓	
Gemcitabine HCl	✓		✓	✓	✓	✓	✓	✓	
Imatinib Mesylate	✓	✓			✓	✓	✓	✓	
Letrozole	✓			✓		✓			
Irinotecan HCl	✓	✓	✓		✓	✓	✓	✓	
Irinotecan HCl (Process-2)						✓	✓		
Melphalan HCl	✓	✓	✓					✓	
Oxaliplatin	✓		✓		✓	✓	✓	✓	
Pemetrexed Disodium	✓	✓	✓		✓		✓	✓	
Temozolomide	✓	✓	✓	✓	✓	✓	✓	✓	
Zoledronic Acid	✓	✓				✓			
Pemetrexed Dipotassium (Nonahydrate)	✓	✓			✓				
Anastrozole	✓							✓	

# Product wise DMF filings as on December 31, 2021

Name of the API	US FDA	EU/ EMEA	TPD-Canada	PMDA Japan	TGA & Medsafe-NZ	EDQM	KFDA Korea	GCC & ROW	WHO Market
Clofarabine	✓	✓						✓	
Dimethyl Fumarate	✓				✓			✓	
Axitinib	✓								
Enzalutamide	✓								
Pirfenidone	✓			✓		✓		✓	
Gemcitabine Hydrochloride (Process-2)	✓	✓	✓			✓			
Ibrutinib	✓							✓	
Teriflunomide	✓	✓			✓			✓	
Pomalidomide	✓		✓					✓	
Tranexamic Acid	✓		✓		✓	✓	✓	✓	
Thalidomide	✓	✓						✓	
Sunitinib Malate	✓	✓							
Lenvatinib Mesylate	✓							✓	
Tenofovir Alafenamide Fumarate	✓								
Praziquantel						✓			✓
Tenofovir Disoproxil Fumarate									✓
Cyclophosphonamide	✓					✓		✓	
Prucalopride succinate	✓	✓	✓				✓	✓	
Lenalidomide	✓								
Acebrophylline							✓	✓	
Sorafenib (Base)							✓		
Sunitinib (Base)	✓	✓							

# Product wise DMF filings as on December 31, 2021

Name of the API	US FDA	EU/ EMEA	TPD-Canada	PMDA Japan	TGA & Medsafe-NZ	EDQM	KFDA Korea	GCC & ROW	WHO Market
Nifedipine	✓								
Phenylephrine hydrochloride	✓								
Nilotinib	✓								
Varenicline tartrate	✓	✓							
Cabazitaxel	✓	✓							
Glycopyrronium bromide						✓			



# Discussion of Formulations Segment

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## Key strengths of the business

- Vertically integrated backed by in-house R&D and innovative APIs with sharp cost competencies
- Range includes liquid and lyophilized injectable, sterile dry powder injections and oral solids in onco & adjuvant therapies
- Strong portfolio of NDDS/value added product pipeline
- Targeted sales of complex products in key regulated/RoW markets

## Way forward

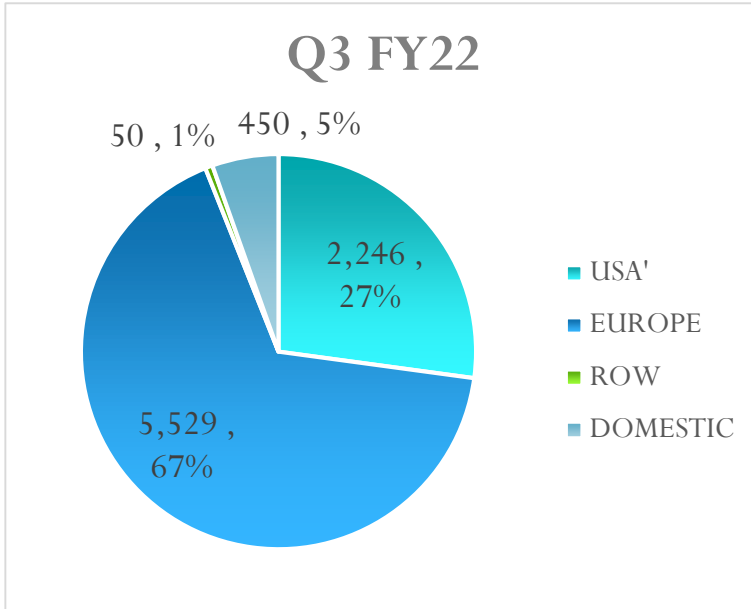
- Partial remediation towards USFDA import alert complete
  - Submission of MCAP (Compliance Plan) to FDA in Q4
- Continue the hedging strategy to de-risk against single site operations
- Continue focus on niche and value-added products portfolio development
  - Strong strategic partnership model to enhance reach



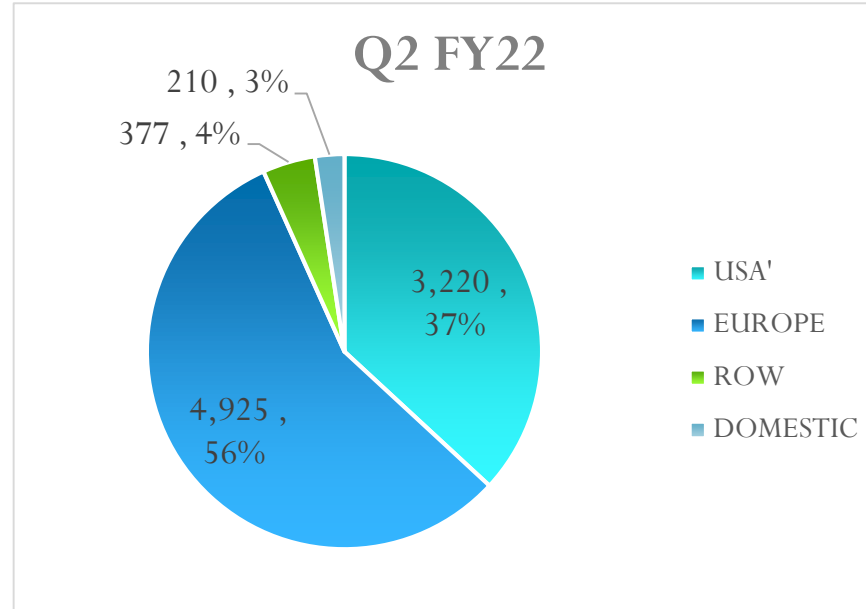
# Formulation - Highlights

## Revenue Split

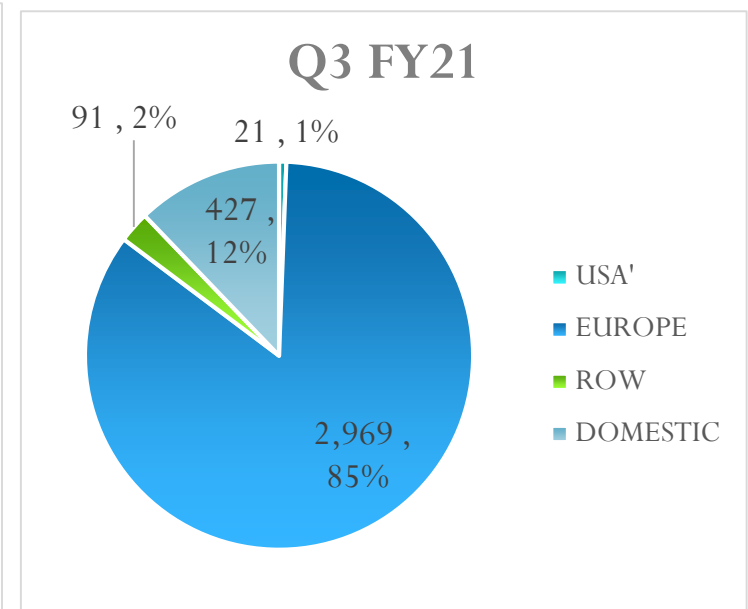
(Rs. In Lakhs)



**Rs. 8,276**



**Rs. 8,732**



**Rs. 3,509**

- Completed 2 site transfer projects
- Won 2 year tender for supply of Dimethyl Fumurate in Saudi Arabia through partner
- Received approval for Pemetrexed RTU for the EU market
- Remote record review by USFDA of QC Lab at Bangalore successfully completed without any observations

# Formulation Product Pipeline as on December 31, 2021

Regulatory Submissions	Filings	Approved (Including Tentative)	Pending
- US ANDA: SML	26	13	13
- US NDA: SML	03	01	02
- US ANDA: Customers	18	13	05
<b>TOTAL (In US)</b>	<b>47</b>	<b>27</b>	<b>20</b>
- EU Filing	25	19	06
- Row Filing	279	95	184
<b>TOTAL (In EU &amp; ROW)</b>	<b>304</b>	<b>114</b>	<b>190</b>
<b>GRANDTOTAL</b>	<b>351</b>	<b>141</b>	<b>210</b>



# Discussion of Biologicals

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## Key strengths of the business

- Strong R&D with focus on difficult products
- World class manufacturing facility
- Development of 1 NBE and 6 biosimilars in limited competition space with significant cost advantage
- 2 products in human clinical & 1 in animal clinicals
- Strategic partnerships in vaccine manufacturing

## Way forward

- First product launch in India expected in Q3/Q4 of FY22-23
- Strategic tie-ups for the international market
- Capture low hanging fruits exploring additional vaccine / MABs manufacturing tie-ups



# Other Updates

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# Patents Status as on December 31, 2021

Patents	Filings	Granted	Pending
- API	208	45	163
- Formulation*	182	35	147
- Films Topical & Transdermal	61	6	55
- Biologicals	12	5	7
- Others	22	5	17
<b>TOTAL</b>	<b>485</b>	<b>96</b>	<b>389</b>

\* Formulation numbers includes the Patents of FTF Pharma Pvt Ltd Ahmedabad, a wholly owned subsidiary of Shilpa Medicare Ltd

# Manufacturing Excellence

## Dharwad



- Biologicals Manufacturing plant & R&D Facility

## Jadcherla Unit



- Formulations (Onco & Adjuvant Therapy)
- of Onco – Injectable & Oral)

## Bengaluru Unit



- TDS & ODF Manufacturing Facility & Formulation R&D

## Hyderabad



- Formulations (Oral Dissolving Films)
- Bio Analytical Lab, Pharmacovigilance Lab & Quality control lab

## Raichur Unit I & II



- API (Oncology – Non-Oncology)
- API (Oncology – Non-Oncology) and R&D API
- CRAMS
- Peptide
- Polymer

## Ahmedabad



- CRO & CDMO
- R&D Formulation

# About Shilpa Medicare Ltd.

*Shilpa Medicare Limited (SML) started its operations as API manufacturer way back in 1989 at Raichur, Karnataka- India. Today Shilpa Medicare Limited is a global brand in manufacturing and supplying of affordable API and Formulation globally in different regulated markets.*

*Shilpa Medicare has been on path of expansion ever since its inception. With a regulatory recognized manufacturing set up and excellent scientific expert team in place, Shilpa Medicare has since been on a steady growth path. Currently they are one of the leaders in the Oncology market and offer a complete range of products in this segment spanning across APIs, formulations both in terms of R&D and manufacturing capabilities. Further to consolidate in field of Oncology, API and formulations, they are striving to put in efforts in field of novel drug delivery systems and biotech products along with widening their focus to other therapy areas. Where Shilpa Medicare Ltd is today is the result of their constant endeavors for more than three decades.*



**Siddharth Rangnekar**  
**Karl H Kolah**



**CDR India**



**+91 22 6645 1209 / 1220**



**[siddharth@cdr-india.com](mailto:siddharth@cdr-india.com)**  
**[karl@cdr-india.com](mailto:karl@cdr-india.com)**





# Thank You