



Medical Design & Manufacturing

MD&M

Minneapolis

At the Minneapolis Convention Center
in Minneapolis, MN

THURSDAY, OCTOBER 22, 2009

COURSE MATERIALS FOR SESSION 301::

***NEW STRATEGIES FOR MANAGING
OUTSOURCED PRODUCT DEVELOPMENT AND
MANUFACTURING***





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VICE PRESIDENT OF PRODUCT DEVELOPMENT*
ACIST MEDICAL SYSTEMS, INC.



Acist Medical Systems (OEM)

is a pioneer and a market leader of
Advanced Contrast Imaging System
Technology in the fields of cardiology and
radiology



In pursuit of the perfect image.



RICK LAFOND

PURCHASING MANAGER
MEDICAL GRAPHICS CORPORATION



Medical Graphics Corporation (OEM)

is the leader in providing innovative
technology for cardiorespiratory diagnostics.





DAN DARST

VICE PRESIDENT OF ENGINEERING
WORRELL, INC.

Worrell, Inc. (ID/MD Firm):

Focused on solving complex
business challenges through the
use of sophisticated design and
research methods





JON BARRETT

ENGINEERING MANAGER

WHITEBOARD PRODUCT SOLUTIONS



WhiteBoard, formerly known as Leisure Product Solutions, is a trusted destination where the client and designers, engineers, and builders can work as a team to develop winning product solutions.

(ID/MD Firm)

KEN SCHWEITZ

PRESIDENT
PREMOLD CORP.

Premold Corp. (Parts Supplier):

is a low quantity injection molder for
the Life Sciences industry



PREMOLD CORP.



JULIE COSICH

MARKETING DEVELOPMENT DIRECTOR
HUI MFG.



HUI Mfg. (Parts Supplier):

Designer and manufacturer of custom metal fabricated products including medical, industrial, and computer carts and enclosures





GREG RIEMER

CHIEF OPERATING OFFICER
MRPC



MRPC (Parts Supplier):

A single-source provider of innovative
medical device components and
assemblies



I. INTRODUCTION

A. THE NEW APPROACH TO PRODUCT DEVELOPMENT AND MANUFACTURING TEAMS

1. MORE AND MORE OEM'S OF MEDICAL AND LAB EQUIPMENT OUTSOURCE THEIR PEAK NEEDS FOR INDUSTRIAL AND MECHANICAL DESIGN (ID & MD)
2. MORE OEM'S ALSO OUTSOURCE THE MANUFACTURE OF THE EQUIPMENT
3. CONTRACT MANUFACTURERS (CM) SPECIALIZE IN REGULATORY COMPLIANCE, PROCUREMENT SYSTEMS AND QUALITY SYSTEMS





I. INTRODUCTION (CON'T)

B. UNDERSTANDING THE NEW NEEDS

1. IN THE 80'S & 90'S ENGINEERING AND MANUFACTURING DEPARTMENTS FOCUSED ON COMMUNICATION
 - A) EARLY INVOLVEMENT
 - B) "DON'T THROW THE DESIGN OR INFORMATION OVER THE FENCE" TO NEXT DEPARTMENT.
2. COMMUNICATION, SPEED TO MARKET, DEVELOPMENT COSTS AND CHANGE CONTROL WERE CHALLENGES IN THE 80'S AND 90'S EVEN WHEN ALL THE ENTITIES WORKED FOR THE SAME COMPANY.
3. DUE TO OUTSOURCING, AN EVEN BIGGER NEED TO FORM WELL SYNCHRONIZED TEAMS BETWEEN THESE PLAYERS: ID, MD, CM, OEM & PARTS SUPPLIERS



I. INTRODUCTION (CON'T)

C. THE GOAL

1. OEM'S WANT:

- A) FAST, MINIMUM COST PRODUCT DEVELOPMENT
- B) MINIMUM TOOLING AND PART COSTS FROM COMPONENTS SUPPLIERS
- C) SHORTEST POSSIBLE LEAD TIMES FOR TOOLING



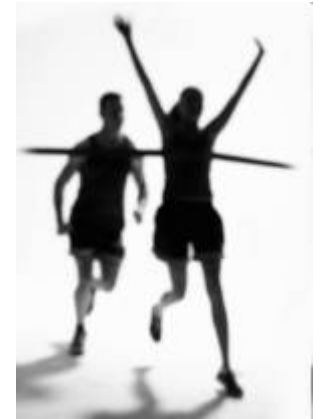


I. INTRODUCTION (CON'T)

C. THE GOAL (CON'T)

1. OEM'S WANT (CON'T):

- D) MINIMAL PROBLEMS AT PRODUCTION START-UPS
- E) COST EFFECTIVE MANUFACTURING WITH MINIMAL PROBLEMS
- F) PRODUCTION TEAMS THAT WORK WELL TOGETHER TO MINIMIZE COSTS AND PROBLEMS





II. WORKING WITH ID AND MD FIRMS

A. SELECT FIRMS WITH PROVEN, SUCCESSFUL RECORDS DOING WHAT YOU NEED DONE.
LOOK FOR:

1. A SUCCESSFUL RECORD OF DESIGNING SIMILAR PRODUCTS FOR SIMILAR INDUSTRIES
2. EXPERIENCE TO DESIGN FOR THE MANUFACTURING PROCESSES THAT ARE VIABLE FOR YOUR PRODUCTS
3. SATISFIED CUSTOMERS
4. SUFFICIENT RESOURCES TO HANDLE YOUR PROJECT





II. WORKING WITH ID AND MD FIRMS (CON'T)

B. ESTABLISH DELIVERABLES

1. WRITE DEFINITION OF WHAT THE OEM WANTS THE ID AND MD FIRMS TO DELIVER
2. MAKE DELIVERABLES AS MEASURABLE AS POSSIBLE.
3. ESTABLISH A SCHEDULE WITH MILESTONES TO CHECK PROGRESS DURING THE PROJECT



II. WORKING WITH ID AND MD FIRMS (CON'T)

B. ESTABLISH DELIVERABLES (CON'T)

4. CLASSIFY PRODUCT SPECIFICATIONS AS “MUSTS” AND “WANTS
5. CLASSIFY “MUSTS” AS HIGH OR LOW RISK
 - A) ASSOCIATE WIDE OR NARROW COST RANGE ESTIMATES WITH HIGH OR LOW RISK SPECIFICATIONS





II. WORKING WITH ID AND MD FIRMS (CON'T)

C. INFORMATION ID AND MD FIRMS WILL NEED

1. TEAM MEMBER NAMES & RESPONSIBILITIES AT THE OEM
2. AN EFFECTIVE COMMUNICATION CONTACT PERSON AT THE OEM IS IMPORTANT
3. A GOOD DEFINITION OF THE PRODUCT AND THE DELIVERABLES
 - A) THE BETTER YOU DEFINE WHAT YOU WANT TO END UP WITH, THE MORE EFFECTIVE YOUR ID AND MD FIRMS CAN BE
 - B) AVOID SOME OEM TEAM MEMBERS JOINING THE PROJECT LATE AND MAKING CHANGES BECAUSE THEY DIDN'T HAVE SUFFICIENT INPUT AT THE START
4. A SCHEDULE WITH MILESTONES



II. WORKING WITH ID AND MD FIRMS (CON'T)

D. HOW TO HANDLE CHANGES

1. COORDINATE CHANGES BETWEEN TEAM MEMBERS OR COMPANIES LIKE YOU WOULD WITH PRODUCTION ECO'S
 - A) KEEP ALL NECESSARY PARTIES INFORMED
2. EFFECTS ON DESIGN COST, PART COST, TOOL COSTS, ASSEMBLY COSTS, LEAD TIMES, ETC. CAN ALL BE IDENTIFIED, CONSIDERED AND COORDINATED





II. WORKING WITH ID AND MD FIRMS (CON'T)

D. HOW TO HANDLE CHANGES (CON'T)

3. KEEP A RECORD OF ALL CHANGES AND THEIR EFFECTS ON COSTS AND SCHEDULES
4. CHANGES CAN BE HANDLED SIMULTANEOUSLY AND RAPIDLY INSTEAD OF SEQUENTIALLY
 - A) IN THE END YOU WON'T SAVE TIME OR MONEY BY LEAVING A TEAM MEMBER OUT OF THE CHANGE DECISIONS





II. WORKING WITH ID AND MD FIRMS (CON'T)

E. RESULTS YOU SHOULD EXPECT

1. WITH A WELL THOUGHT-OUT PRODUCT DEFINITION AND GOOD COMMUNICATIONS WITH ALL THE NECESSARY TEAM MEMBERS, EXPECT A COST EFFECTIVE PRODUCT DESIGN THAT MEETS ALL OF THE AGREED UPON REQUIREMENTS
2. THERE SHOULD BE NO COST SURPRISES FROM YOUR ID OR MD FIRM, YOUR CM OR YOUR PARTS SUPPLIERS BECAUSE COMMUNICATION AND INVOLVEMENT WAS GOOD DURING THE DESIGN PROCESS



II. WORKING WITH ID AND MD FIRMS (CON'T)

E. RESULTS YOU SHOULD EXPECT (CON'T)

3. NO DESIGN CHANGES SHOULD BE NEEDED BECAUSE OEM AND SUPPLIERS REVIEWED THE DESIGN AND PROVIDED INPUT ALONG THE WAY
4. YOU SHOULD NOT NEED TO RE-ENGAGE THE MD TO MAKE CHANGES TO ACCOMMODATE MANUFACTURING PROCESSES
5. YOUR IN-HOUSE STAFF SHOULD NOT NEED TO REVISE THE DESIGNS TO FIT THEIR NEEDS





III. WORKING WITH YOUR PART SUPPLIERS

A. SELECT FIRMS WITH PROVEN, SUCCESSFUL RECORDS DOING WHAT YOU NEED DONE. LOOK FOR:

1. A SUCCESSFUL RECORD OF PRODUCING SIMILAR PARTS FOR SIMILAR INDUSTRIES
2. SATISFIED CUSTOMERS
3. SUFFICIENT RESOURCES TO HANDLE YOUR PROJECT





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

B. WHEN TO GET THEM INVOLVED

1. GET THEM INVOLVED EARLY TO PROVIDE FEEDBACK ON DESIGN CONCEPTS SO YOU CAN DETERMINE DESIGN DIRECTIONS
2. KEEP THEM INVOLVED ALL DURING THE ID AND MD PROCESS
 - A) INPUT FROM PARTS SUPPLIERS SHOULD MAKE THE DESIGNS EVOLVE QUICKLY AND EFFICIENTLY
 - B) AVOID LOST TIME AND SURPRISES AT THE END OF A PROJECT BY SUSTAINING INPUT FROM KEY SUPPLIERS



III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

C. INPUT THEY SHOULD PROVIDE

1. INPUTS ON PART COST, QUALITY, PRODUCTION LEAD TIMES, TOOLING COSTS, TOOLING LEAD TIMES, DESIGN OPTIONS, COSTS/BENEFITS, ETC
 - A) THE SAME INPUTS AN OEM'S IN-HOUSE MANUFACTURING PERSONNEL SUPPLIED UNDER THE OLD, VERTICALLY INTEGRATED ORGANIZATIONS





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

C. WHAT INPUT THEY SHOULD PROVIDE (CON'T)

2. USE YOUR PRODUCTION PARTS SUPPLIERS FOR PROTOTYPES WHENEVER POSSIBLE
 - A) THIS WILL MINIMIZE YOUR COMMUNICATION WORKLOAD AND GIVE SUPPLIERS EARLY EXPERIENCE WITH THE PARTS
 - B) THE PROTOTYPE PARTS SHOULD BE REPRESENTATIVE OF THE PRODUCTION PARTS





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

D. SETTING COMMUNICATION RULES AND CHANNELS

1. ESTABLISH A PROJECT LEADER TO COORDINATE ALL COMMUNICATIONS AND TO ENSURE THAT ALL TEAM MEMBERS ARE INFORMED
2. ESTABLISH A LEAD PERSON AT EACH TEAM MEMBER'S COMPANY AND HAVE ALL COMMUNICATIONS FOR THAT COMPANY GO THROUGH THEM
 - A) THIS LEAD PERSON SHOULD COORDINATE THE CHANGE PROCESS FOR THEIR COMPANY AND KEEP A RECORD OF ALL CHANGES AND THEIR EFFECTS





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

D. SETTING COMMUNICATION RULES AND CHANNELS (CON'T)

3. AVOID THE TEMPTATION TO COMMUNICATE DIRECTLY WITH SOMEONE AND LEAVE OUT A TEAM LEADER
 - A) THIS IS LIKE SKIPPING A STEP IN THE INTERNAL ECO PROCESS
 - B) THE RISK IS TOO HIGH THAT MORE TIME AND MONEY WILL BE SPENT IN THE LONG RUN



III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

E. AVOID CONCERNS ABOUT SINGLE QUOTES AND SINGLE SOURCES

1. MANY OEM'S FEAR THAT IF THEY FORM TEAMS TOO EARLY WITH KEY SUPPLIERS THEY WON'T RECEIVE THE BEST PRICES
2. SUPPLIERS ARE USUALLY VERY WILLING TO PROVIDE INPUT ON THEIR AREAS OF EXPERTISE
 - A) SUPPLIERS WANT PRODUCTS TO FLOW THROUGH THEIR FACTORIES EASILY, WITH AS FEW PROBLEMS AS POSSIBLE, WITH THE LEAST RISK OF PROBLEMS OR DELAYS





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

E. AVOID CONCERNS ABOUT SINGLE QUOTES AND SINGLE SOURCES (CON'T)

3. IF THE SUPPLIER EXPRESSES CONCERN ABOUT “LOSING THE BUSINESS AT THE LAST MINUTE TO A VENDOR WHO DIDN’T INVEST ALL THE HARD WORK ALONG THE WAY”, ASK THE SUPPLIER WHAT THEY WOULD BE PROVIDING UNDER THIS WORKING ARRANGEMENT THAT THEY WOULDN’T NORMALLY DO
 - A) IF THEY ARE PROVIDING MORE THAN NORMAL, SOME CONSIDERATION MAY BE DUE



III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

E. AVOID CONCERNS ABOUT SINGLE QUOTES AND SINGLE SOURCES (CON'T)

4. IT'S ALSO FAIR AND ETHICAL TO LET THE SUPPLIERS ON YOUR TEAM KNOW FROM THE START THAT YOU'LL BE CHECKING PRICES WITH THEIR COMPETITORS AT KEY POINTS ALONG THE WAY
 - A) SUPPLIERS NEED TO PROVIDE GOOD INPUT IN A TIMELY MANNER AND BE COMPETITIVE WITH COSTS AND LEAD TIMES TO STAY ON YOUR DEVELOPMENT TEAM
 - B) GOOD SUPPLIERS RESPECT YOUR SOUND BUSINESS MANAGEMENT, YOUR STRAIGHT FORWARD COMMUNICATION AND ARE NOT AFRAID OF FAIR COMPETITION





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

E. AVOID CONCERNS ABOUT SINGLE QUOTES AND SINGLE SOURCES (CON'T)

4. IT'S ALSO FAIR AND ETHICAL....(CON'T)

- C) SUPPLIERS WILL FEEL MORE COMFORTABLE IF THEY KNOW THAT ALL THE DECISION MAKERS HAVE BEEN INVOLVED FROM THE TEAM MEMBER COMPANIES
- D) LET SUPPLIERS KNOW THEIR CONTRIBUTIONS AND TEAM MEMBERSHIPS HAVE VALUE WHEN YOU SELECT YOUR PRODUCTION SUPPLIERS





III. WORKING WITH YOUR PART SUPPLIERS (CON'T)

E. AVOID CONCERNS ABOUT SINGLE QUOTES AND SINGLE SOURCES (CON'T)

5. PERIODICALLY ASKING A SUPPLIER'S COMPETITORS TO COMMENT ON A DESIGN CAN HELP GUARD AGAINST INCORPORATING DESIGN FEATURES OR SPECIFICATIONS THAT ARE TOO UNIQUE TO THE SUPPLIER ON YOUR TEAM
 - A) THIS IS IMPORTANT TO THE OEM IN CASE OF NATURAL DISASTERS OR OTHER SUPPLY INTERRUPTIONS





IV. WORKING WITH YOUR CM

A. SELECT FIRMS WITH PROVEN, SUCCESSFUL RECORDS DOING WHAT YOU NEED DONE.

LOOK FOR:

1. A SUCCESSFUL RECORD OF PRODUCING SIMILAR PRODUCTS FOR SIMILAR INDUSTRIES
2. EXPERIENCE AND SUCCESS WITH MANUFACTURING PROCESSES AND VENDORS THAT CAN SUPPORT YOUR PRODUCTS
3. SATISFIED CUSTOMERS
4. SUFFICIENT RESOURCES TO HANDLE YOUR PROJECT



IV. WORKING WITH YOUR CM (CON'T)

B. ESTABLISH A CONTRACT

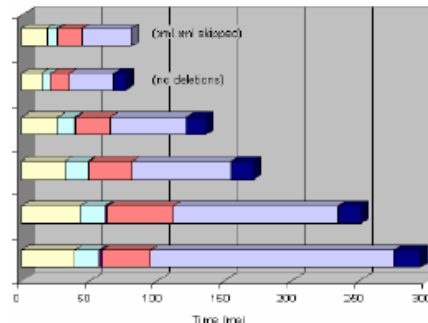
1. DEFINE YOUR PRODUCT OR WHAT YOU WANT AS THOROUGHLY AS POSSIBLE: SIZES, PERFORMANCE CRITERIA, COLORS, DURABILITY, ETC

2. SPECIFY WHAT RESPONSIBILITIES YOU WANT YOUR CM TO HAVE
 - A) MD WORK
 - B) PROCESS SELECTION
 - C) VENDOR SELECTION
 - D) PURCHASED PART PRICES
 - E) PLACING PURCHASE ORDERS
 - F) QUALITY CONTROL WORK WITH PARTS SUPPLIERS
 - G) DELIVERY PERFORMANCE OF PARTS SUPPLIERS

IV. WORKING WITH YOUR CM (CON'T)

B. ESTABLISH A CONTRACT (CON'T)

3. SPECIFY KEY MILESTONES TO MEET WITH DATES
4. MAKE DELIVERABLES AND SPECIFICATIONS AS MEASURABLE AS POSSIBLE
 - A) RELY ON INDUSTRY STANDARDS OR SUPPLIERS' IN-HOUSE SPECIFICATIONS AS MUCH AS POSSIBLE





IV. WORKING WITH YOUR CM (CON'T)

C. INFORMATION THE CM WILL NEED

1. NAME, CONTACT INFORMATION AND AREAS OF RESPONSIBILITIES FOR ALL TEAM MEMBERS
2. GOOD DEFINITIONS OF THE PRODUCT AND THE DELIVERABLES
 - A) THE BETTER YOU DEFINE WHAT YOU WANT, THE MORE EFFECTIVE YOUR CM CAN BE
 - B) PRODUCTION DETAILS LIKE ORDER LEAD TIMES, ORDER RELEASE QUANTITIES, PRICE GOALS, PACKAGING REQUIREMENTS, ASSEMBLY REQUIREMENTS, ETC
3. SCHEDULES WITH MILESTONES



IV. WORKING WITH YOUR CM (CON'T)

D. HOW TO HANDLE CHANGES

1. DURING THE DEVELOPMENT PROCESS, THE TEAM LEADER AT THE CM SHOULD COORDINATE CHANGES FOR THE CM
 - A) THEY SHOULD KEEP A RECORD OF ALL CHANGES AND THEIR EFFECTS ON COSTS AND SCHEDULES

2. DURING PRODUCTION THE TEAM LEADER AT THE CM, OR WHOMEVER THE OEM DESIGNATES, SHOULD COORDINATE CHANGES BETWEEN THE TEAM MEMBER COMPANIES
 - A) OBTAIN INPUT FROM THE TEAM MEMBER COMPANIES SO ALL ASPECTS OF A CHANGE CAN BE CONSIDERED



IV. WORKING WITH YOUR CM (CON'T)

E. RESULTS YOU SHOULD EXPECT

1. NO CHANGES REQUIRED TO MAKE THE PRODUCT MANUFACTURABLE
2. COST EFFECTIVE PRODUCTS MANUFACTURED TO THE AGREED UPON REQUIREMENTS
3. PRODUCTION DOCUMENTATION THAT MEETS YOUR REQUIREMENTS





V. HOW MULTI-COMPANY TEAMS SHOULD WORK

- A. EACH SUPPLIER ON YOUR PRODUCT DEVELOPMENT AND PRODUCTION TEAM SHOULD PROVIDE INPUT FROM THEIR AREAS OF EXPERTISE

- B. YOUR SUPPLIERS SHOULD BE ABLE TO FUNCTION AND CONTRIBUTE SIMILAR AS IF THEY WERE AN IN-HOUSE DEPARTMENT PROVIDING THAT SERVICE



V. HOW MULTI-COMPANY TEAMS SHOULD WORK (CON'T)

C. A TEAM LEADER SHOULD BE DESIGNATED. THE LEADER SHOULD HAVE GOOD COMMUNICATION SKILLS AND UNDERSTAND WHAT INPUT IS NEEDED FROM EACH TEAM MEMBER AND WHEN IT'S NEEDED. THEIR COMMUNICATION SKILLS SHOULD NOT ONLY ALLOW THEM TO COMMUNICATE CLEARLY WITH OTHER TEAM MEMBERS BUT ALSO TO ENSURE THE OTHER TEAM MEMBERS ARE COMMUNICATING EFFECTIVELY WITH EACH OTHER.



V. HOW MULTI-COMPANY TEAMS SHOULD WORK (CON'T)

D. RESULTS YOU SHOULD EXPECT

1. WITH :
 - A) GOOD COMMUNICATION CHANNELS ESTABLISHED
 - B) AN EFFECTIVE PROJECT COORDINATOR
 - C) EVERYONE UNDERSTANDING THEIR ROLES ON THE TEAM
 - D) EVERYONE UNDERSTANDING THE ROLES OF THE OTHER TEAM MEMBERS

EXPECT RESULTS SIMILAR TO IF ALL FUNCTIONS WERE PERFORMED IN-HOUSE BY CO-WORKERS
2. EACH SUPPLIER SHOULD PROVIDE EXPERTISE IN THEIR AREAS OF SPECIALTY
3. EACH SUPPLIER/TEAM MEMBER SHOULD ADD TO OR ENHANCE THE PROJECT AND PRODUCT



V. HOW MULTI-COMPANY TEAMS SHOULD WORK (CON'T)

D. RESULTS YOU SHOULD EXPECT (CON'T)

4. PRODUCT DESIGNS THAT MEET OR EXCEED YOUR SPECIFICATIONS, DELIVERED ON TIME, WITHIN YOUR BUDGET
5. EACH TEAM MEMBER AND OTHER KEY PEOPLE IN YOUR ORGANIZATION UNDERSTANDING HOW THE PROJECT MET YOUR ORIGINAL OR REVISED REQUIREMENTS
6. CONGRATULATIONS FOR A JOB WELL DONE!